

US3342354 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:09:30

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US3342354

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

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Participant ID

US3342354

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

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US3342354

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:13:15

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	52
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	False
Black	True
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) 29 Mar 2021 22:13:14

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	08 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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) 29 Mar 2021 22:13:14

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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) 29 Mar 2021 22:13:15

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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) 29 Mar 2021 22:13:14

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Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	ANXIETY
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: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	DEPRESSION
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: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 22:13:15

Generated On: 09 Jun 2021 17:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 11:30
Height ( <i>xxx.x</i> )	165.5 cm
Weight ( <i>xxx.x</i> )	66.4 kg
BMI ( <i>xxx.x</i> )	24.24220 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	67 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:13:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 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) 29 Mar 2021 22:13:14

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Date of assessment (dd MMM yyyy) 08 OCT 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 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 22:13:15

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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**

UNEMPLOYED

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Mar 2021 22:13:15

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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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

What was the date of randomization? (dd MMM yyyy) 13 OCT 2020

What was the participant's randomization number? 147101

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) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:39
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:14
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 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) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 OCT 2020

What was the treatment time? (00:00-23:59) 11:38 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 11:38

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	11:26 (24 HR)
Collection date and time (derived)	13 OCT 2020 11:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:28	13 OCT 2020 11:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

13 OCT 2020 12:18

PC Open Date & Time

13 OCT 2020 11:58

PC Close Date & Time

13 OCT 2020 14:28

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	13 OCT 2020 15:29
PC Open Date & Time	13 OCT 2020 15:23
PC Close Date & Time	14 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 13:43

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

15 OCT 2020 19:58

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 10:30

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 19:49

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

18 OCT 2020 23:23

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 12:19

PC Open Date & Time

13 OCT 2020 11:58

PC Close Date & Time

13 OCT 2020 14:28

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 15:29

PC Open Date & Time

13 OCT 2020 15:23

PC Close Date & Time

14 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 13:44

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 19:59

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 10:30

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 19:50

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 23:23

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 12:20
PC Open Date & Time	13 OCT 2020 11:58
PC Close Date & Time	13 OCT 2020 14:28

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 15:30
PC Open Date & Time	13 OCT 2020 15:23
PC Close Date & Time	14 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2405

EAB) (1725)

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 13:45
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2405

EAB) (1725)

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 10:31
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2405

EAB) (1725)



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:50
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2405

EAB) (1725)

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 23:24
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Yes ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342354

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342354

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:59
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 12:24
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 12 NOV 2020 11:50

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



US3342354

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 NOV 2020
Collection time (00:00-23:59)	11:33 (24 HR)
Collection date and time (derived)	12 NOV 2020 11:33

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Collection date (dd MMM yyyy)			12 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	12 NOV 2020 11:35
Nasopharyngeal Swab 2	No		

US3342354

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

12 NOV 2020 12:26

PC Open Date & Time

12 NOV 2020 12:10

PC Close Date & Time

12 NOV 2020 14:40

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	12 NOV 2020 20:11
PC Open Date & Time	12 NOV 2020 15:35
PC Close Date & Time	13 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

13 NOV 2020 14:08

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	14 NOV 2020 18:32
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 NOV 2020 17:35

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

94.2 °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

16 NOV 2020 22:11

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

17 NOV 2020 23:09

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

19 NOV 2020 00:01

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 NOV 2020 12:23

PC Open Date & Time

12 NOV 2020 12:10

PC Close Date & Time

12 NOV 2020 14:40

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 NOV 2020 20:07

PC Open Date & Time

12 NOV 2020 15:35

PC Close Date & Time

13 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 NOV 2020 14:04

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 NOV 2020 18:29

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 17:29

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 22:11

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 23:08

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 00:00

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 12:22
PC Open Date & Time	12 NOV 2020 12:10
PC Close Date & Time	12 NOV 2020 14:40

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 20:06
PC Open Date & Time	12 NOV 2020 15:35
PC Close Date & Time	13 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	13 NOV 2020 14:03
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 18:28
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 17:29
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 22:10
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 23:08
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

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

US3342354

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:55

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3342354

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 DEC 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

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	11:57 (24 HR)
Vital Signs Date and Time (derived)	9 DEC 2020 11:57
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	77 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342354

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3342354

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 DEC 2020
Collection time (00:00-23:59)	12:25 (24 HR)
Collection date and time (derived)	9 DEC 2020 12:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:07:56

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 61
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 DEC 2020 15:13:21
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 07:15:26
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59



US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 16:16:11
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	31 DEC 2020 15:32:11
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

<b>TIMEPOINT</b>	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	07 JAN 2021 23:54:43
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 14:08:34

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:03:47

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 15:21:26
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59



US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 08:18:38
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 08:34:33

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 00:46:38

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 15:53:25

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 18:19:21

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:00:48

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 02:21:40

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 01:11:22

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 17:03:29

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 11:44:08

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 APR 2021 09:05:25
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 208

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 229

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 257

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 278

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 292

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 299

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 327

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 348

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 362

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**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°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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 383

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 425

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 453

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 467

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 488

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3342354**

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

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

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3342354**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 516

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

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

**US3342354**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3342354**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 530

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 551

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3342354**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 656

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 663

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

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



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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 ☐

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 705

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 726

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

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

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

**US3342354**

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

**Form: Safety Follow Up Diary**

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

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3342354**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2022 23:59

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2022 23:59

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US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2022 23:59

US3342354

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:09:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		13 MAR 2021 15:53:46



US3342354

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342354

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 15:57:32

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:57:32

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3342354**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3342354

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3342354

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3342354

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3342354**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342354

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3342354**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:09:30**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	19 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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US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Date of updated informed consent ( <i>dd MMM yyyy</i> )	19 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> )	19 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

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 13:35
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 14:14 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 14:14

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

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

14:02 (24 HR)

Collection date and time (derived)

28 JAN 2021 14:02

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	14:04
Collection Date and Time (derived)	28 JAN 2021 14:04



US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

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*

US3342354

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3342354

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:59
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 13:27
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3342354

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3342354

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 12:57 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 12:57

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



US3342354

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342354

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 22:13:14

Generated On: 09 Jun 2021 17:09:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342354

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:57:31

Generated On: 09 Jun 2021 17:09:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	OLD57

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:57:31

Generated On: 09 Jun 2021 17:09:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 APR 2021
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	06 APR 2021 11:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342354

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:57:31

Generated On: 09 Jun 2021 17:09:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3342354

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:57:31

Generated On: 09 Jun 2021 17:09:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	11:59 (24 HR)
Collection date and time (derived)	6 APR 2021 11:59

US3342354

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:45:27

Generated On: 09 Jun 2021 17:09:30

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

AEID	USA-US203-2020-MRNA-1273-P30 1000011
Adverse event	DIABETIC KETOACIDOSIS
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)	11 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	13 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

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PATIENT'S SYMPTOMS BEGAN  
THE EVENING OF 11DEC2020. PT  
REPORTS SHE WAS ADMITTED  
TO THE HOPSITAL ON THE  
NIGHT OF 11DEC2020 DUE TO  
VOMITING AND  
UNCONTROLLED BLOOD  
SUGAR IN THE 400'S. PATIENT  
STATES THAT SHE STAYED IN  
THE ICU FOR 1 DAY ON AN  
INSULIN DRIP AND THEN WAS  
DISCHARGED ON 13DEC2020  
ONCE BLOOD SUGAR WAS  
CONTROLLED AND STABLE.  
PATIENT STATES THAT SHE  
HAD RAN OUT OF DM TYPE II  
MEDICATIONS CAUSING THIS  
EVENT.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

---

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

AEID	
Adverse event	EXACERBATION OF DEPRESSION
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)	23 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

AEID	
Adverse event	EXACERBATION OF ANXIETY
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)	23 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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AEID	USA-US203-2021-MRNA-1273-P30 1000016
Adverse event	SEPTICEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	18 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 APR 2021
Hospital Discharge Date (dd MMM yyyy)	24 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

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Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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PT. WENT TO NORTH EAST  
METHODIST HOSPITAL ON 18  
APR 2021 DUE TO SX OF UTI  
AND HIGH BLOOD SUGAR.  
WHILE IN HOSPITAL PT. HAD  
DIFFICULTY BREATHING.  
AFTER CT SCAN PHYSICIAN  
"FOUND FLUID IN [HER]  
CHEST". PT. ADMITTED TO "ICU  
FOR HEART PTS" WHERE THEY  
STAYED FOR 3 DAYS. PT.  
PRESCRIBED FUROVSEMIDE 20  
MG BID, CARVEDILOL 3.125 MG  
BID AND LISINOPRIL 5 MG QD.  
PT. DISCONTINUED  
PRAVASTATIN ALL ON  
20APR2021. PT. DISCHARGED  
FROM HOSPITAL ON 24APR2021.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Mar 2021 13:41:29

Generated On: 09 Jun 2021 17:09:30

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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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 2013	
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) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication SITAGLIPTIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 DEC 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 (5)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY & DEPRESSION

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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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 (6)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY & DEPRESSION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN 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) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication 70/30 INSULIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 42

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

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 (8)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1985	
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 (9)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE POST VACCINE #2  
AR

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication OXCARBAZEPINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY AND DEPRESSION  
EXACERBATION

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	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)		5 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication SITAGLIPTIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 DEC 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 (13)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication NOVOLOG 70/30 INSULIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 42

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 QAM

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 DEC 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 (14)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication NOVOLOG 70/30 INSULIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 32

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 QPM

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 DEC 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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Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication REGULAR INSULIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

Dose per administration 8

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 (15)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication CEFTRIAXONE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

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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Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication IOPAMIDOL

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

Dose per administration 75

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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Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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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 checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication ONDASTERON

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

Dose per administration 4

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 (18)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication HUMULIN R INSULIN DRIP

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

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 (19)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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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 checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 22:18:08

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Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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 (20)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input 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"/>

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS AE

Dose per administration 150

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify ML/HR

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication SEPTICEMIA SAE

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication SEPTICEMIA SAE

Dose per administration 3.125

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☒  
No ☐

Indication SEPTICEMIA SAE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 30 Apr 2021 22:18:08

Generated On: 09 Jun 2021 17:09:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Mar 2021 13:41:29

Generated On: 09 Jun 2021 17:09:30

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Mar 2021 13:41:29

Generated On: 09 Jun 2021 17:09:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 DEC 2020	CHEST XRAY	Adverse Event	
12 DEC 2020	ABDOMINAL/PELVIS CT WITH CONTRAST	Adverse Event	

US3342354

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:09:30

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3342354

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:09:30

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/DEC/2020 10:10
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

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/JAN/2021 16:37
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



US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 08:37
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

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 22:18:09

Generated On: 09 Jun 2021 17:09:30

SAEID	USA-US203-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	30/APR/2021 09:24
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.	True

Audit

US3342354 (Prod: Tekton Research- Austin)

**US3342354**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:09:30**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:20:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'US3342354'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Oct 2020 15:37:43

US3342354

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:18

US3342354

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '08 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Oct 2020 15:37:44

US3342354

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:18



**US3342354**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'SCRN'	System	08 Oct 2020 17:42:18

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Per GCL Lab Reconciliation: Swab: Year of birth is recorded as "1968" & Sex is recorded as "Female" in EDC; however, year of birth & Sex is missing in PPD Central lab. Kindly confirm if sex is Female & year of birth 1968 is correct to be updated in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:02:00
Query 'Per GCL Lab Reconciliation: Swab: Year of birth is recorded as "1968" & Sex is recorded as "Female" in EDC; however, year of birth & Sex is missing in PPD Central lab. Kindly confirm if sex is Female & year of birth 1968 is correct to be updated in GCL records.' answered with 'Patient's DOB was confirmed to be (b) (6) 1968 and they are female' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:28:03
User opened query 'Per GCL Lab Reconciliation: Swab: Year of birth is recorded as "1968" & Sex is recorded as "Female" in EDC; however, year of birth & Sex is missing in PPD Central lab. Kindly confirm if sex is Female & year of birth 1968 is correct to be updated in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:44:37
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Oct 2020 15:37:45

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '51'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

**US3342354**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:09:30**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'YEARS'	System	08 Oct 2020 17:42:33

**US3342354**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:09:30**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '52'	System	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33



US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33

US3342354

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:33



US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:07:26
User entered '8 Oct 2020'	Morgan Schulle (b) (4)	08 Oct 2020 17:42:53
	(b) (4), (b) (6)	

**US3342354**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:09:30**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Oct 2020'	System	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2020'	System	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:53

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:53



US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Oct 2020 15:37:44

US3342354

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'I'	System	08 Oct 2020 17:42:59

US3342354

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:09:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:42:59

US3342354

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:09:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:43:05

US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:44:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:44:43
Data point term sent to Coder	System	08 Oct 2020 17:44:27
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	08 Oct 2020 17:44:08

US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:08

US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:08

US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:08



US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:08

US3342354

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:08

**US3342354**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2013'	System	08 Oct 2020 17:44:08

**US3342354**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2013'	System	08 Oct 2020 17:44:08

**US3342354**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:44:08

**US3342354**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:44:08

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:44:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:44:51
Data point term sent to Coder	System	08 Oct 2020 17:45:30
User entered 'Hypertension'	(b) (4), (b) (6)	08 Oct 2020 17:44:56

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:56



**US3342354**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:56

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:56

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:56

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:44:56

**US3342354**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2013'	System	08 Oct 2020 17:44:56

US3342354

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2013'	System	08 Oct 2020 17:44:56

**US3342354**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:44:56

**US3342354**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:44:56



US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:09
Data point term sent to Coder	System	08 Oct 2020 17:47:34
User entered 'Type 2 Diabetes'	(b) (4), (b) (6)	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:46:41

**US3342354**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2013'	System	08 Oct 2020 17:46:41

**US3342354**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2013'	System	08 Oct 2020 17:46:41



US3342354

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:46:41

**US3342354**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:46:41

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:08
Data point term sent to Coder	System	08 Oct 2020 17:47:35
User entered 'Anxiety'	(b) (4), (b) (6)	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:03



**US3342354**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2018'	System	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2018'	System	08 Oct 2020 17:47:03

**US3342354**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:47:03

**US3342354**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:47:03

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:09
Data point term sent to Coder	System	08 Oct 2020 17:47:36
User entered 'Depression'	(b) (4), (b) (6)	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:32



US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2018'	System	08 Oct 2020 17:47:32

**US3342354**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2018'	System	08 Oct 2020 17:47:32

**US3342354**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:47:32

**US3342354**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:47:32

US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:12
Data point term sent to Coder	System	08 Oct 2020 17:48:37
User entered 'Headaches'	(b) (4), (b) (6)	08 Oct 2020 17:48:03

US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:48:03



US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:48:03

US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:48:03

US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:48:03

US3342354

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:48:03

**US3342354**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 1985'	System	08 Oct 2020 17:48:03

**US3342354**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '1985'	System	08 Oct 2020 17:48:03

**US3342354**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:48:03

**US3342354**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	08 Oct 2020 17:48:03



US3342354

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
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)	03 Nov 2020 21:30:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 21:30:30
Data point term sent to Coder	System	03 Nov 2020 21:29:59
User entered 'Postmenopausal'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

US3342354

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2016'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

US3342354

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

**US3342354**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

US3342354

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

US3342354

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:29:07

**US3342354**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'Jan 2016'	System	03 Nov 2020 21:29:07

**US3342354**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '2016'	System	03 Nov 2020 21:29:07



**US3342354**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	03 Nov 2020 21:29:07

**US3342354**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered empty.	System	03 Nov 2020 21:29:07

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:07:40
User entered '8 Oct 2020'	Morgan Schulle (b) (4)	08 Oct 2020 17:51:25
	(b) (4), (b) (6)	

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '11:30'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

**US3342354**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '08 Oct 2020 11:30'	System	12 Nov 2020 18:07:40
User entered '8 Oct 2020 11:30'	System	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '165.5' cm	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25
DataPoint set to visible.	System	08 Oct 2020 17:42:59

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '66.4' kg	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25
DataPoint set to visible.	System	08 Oct 2020 17:42:59



**US3342354**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered '24.24220'	System	08 Oct 2020 17:51:25
DataPoint set to visible.	System	08 Oct 2020 17:42:59

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'kg/m2'	System	08 Oct 2020 17:51:25
DataPoint set to visible.	System	08 Oct 2020 17:42:59

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '67'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'bpm'	System	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25



US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'breaths/min'	System	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '148'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'mmHg'	System	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '83'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User entered 'mmHg'	System	08 Oct 2020 17:51:25

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06

US3342354

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06

US3342354

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:51:35



US3342354

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:07:47
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:51:35

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:07:56
User entered '8 Oct 2020'	Morgan Schulle (b) (4)	08 Oct 2020 17:52:20
	(b) (4), (b) (6)	

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
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)	04 Nov 2020 14:41:28
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 'Condition has been recorded in MH source and EDC.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	03 Nov 2020 21:29:54
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)	01 Nov 2020 16:40:24
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20



US3342354

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:52:20

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08



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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Unemployed'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

**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 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:53:08

US3342354

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:20:57

US3342354

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:20:57



US3342354

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:20:57

US3342354

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'VISIT1'	System	13 Oct 2020 16:20:57

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:58:49

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '147101'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:58:49

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:58:49

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35



US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35

US3342354

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	13 Oct 2020 16:11:35
DataPoint set to visible.	(b) (4) System	08 Oct 2020 17:42:53

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 16:21:52



US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '10:39'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '13 Oct 2020 10:39'	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '72'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52



US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'bpm'	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '14'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'breaths/min'	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '125'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'mmHg'	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '77'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'mmHg'	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52



US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 17:20:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:20:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	13 Oct 2020 17:20:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 16:21:52
User entered empty.	System	13 Oct 2020 16:21:52
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4)	
	(b) (4), (b) (6)	

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12:14' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4), (b) (6)	

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '13 Oct 2020 12:14'	System	13 Oct 2020 17:20:05
User entered empty.	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 17:20:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	13 Oct 2020 17:20:18
User entered '98.2' F reason for change: Data Entry Error	Ethan Shotton (b) (4)	13 Oct 2020 17:20:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 17:20:05
User entered empty; reason for change Data Entry Error	System	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 17:20:05
	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4)	
	(b) (4), (b) (6)	



US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:21:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '67' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4)	
	(b) (4), (b) (6)	

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'bpm'	System	13 Oct 2020 17:20:05
User entered empty.	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '14' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'breaths/min'	System	13 Oct 2020 17:20:05
User entered empty.	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '132' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 17:20:05
User entered empty.	Ethan Shotton (b) (4)	13 Oct 2020 16:21:52
	(b) (4)	
	(b) (4), (b) (6)	

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'mmHg'	System	13 Oct 2020 17:20:05
User entered empty.	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '74' reason for change: Data Entry Error	Ethan Shotton (b) (4)	13 Oct 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:21:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'mmHg'	System	13 Oct 2020 17:20:05
User entered empty.	System	13 Oct 2020 16:21:52

US3342354

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:24:12

US3342354

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:24:12

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) Morgan Schulle (b) (4)	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	Morgan Schulle (b) (4)	13 Oct 2020 16:55:43



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:38'	Morgan Schulle (b) (4)	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '13 Oct 2020 11:38'	System	13 Oct 2020 16:55:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Left Arm (LEFT ARM)'	Morgan Schulle (b) (4)	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'ONCE'	System	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 16:55:43

US3342354

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Oct 2020 15:34:28

US3342354

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 15:34:28

US3342354

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:26'	Morgan Schulle (b) (4)	28 Oct 2020 15:34:28



US3342354

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '13 Oct 2020 11:26'	System	28 Oct 2020 15:34:28

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '13 Oct 2020'	Morgan Schulle (b) (4)	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 15:34:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:28'	Morgan Schulle (b) (4)	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '13 Oct 2020 11:28'	System	28 Oct 2020 15:34:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 15:34:11



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered empty.	System	28 Oct 2020 15:34:11

US3342354

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:22:14

US3342354

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'I'	System	13 Oct 2020 16:22:14

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:17:56', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e6ef60ec-44af-4ed3-8265-cb2247d01155'	System	13 Oct 2020 17:18:37
User entered 'Yes (Y)'	System	13 Oct 2020 17:18:37

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:18:11', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e6ef60ec-44af-4ed3-8265-cb2247d01155'	System	13 Oct 2020 17:18:37
User entered '98.2'	System	13 Oct 2020 17:18:37

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:18:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e6ef60ec-44af-4ed3-8265-cb2247d01155'	System	13 Oct 2020 17:18:37
User entered 'No (N)'	System	13 Oct 2020 17:18:37



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:18:29', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e6ef60ec-44af-4ed3-8265-cb2247d01155'	System	13 Oct 2020 17:18:37
User entered '13 Oct 2020 12:18'	System	13 Oct 2020 17:18:37

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 11:58'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 14:28'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:28:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '39c06a82-3dff-47f6-892a-8e9ce102e8f5'	System	13 Oct 2020 20:29:20
User entered 'Yes (Y)'	System	13 Oct 2020 20:29:20

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:03', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '39c06a82-3dff-47f6-892a-8e9ce102e8f5'	System	13 Oct 2020 20:29:20
User entered '98.6'	System	13 Oct 2020 20:29:20

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:09', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '39c06a82-3dff-47f6-892a-8e9ce102e8f5'	System	13 Oct 2020 20:29:20
User entered 'No (N)'	System	13 Oct 2020 20:29:20

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '39c06a82-3dff-47f6-892a-8e9ce102e8f5'	System	13 Oct 2020 20:29:20
User entered '13 Oct 2020 15:29'	System	13 Oct 2020 20:29:20



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 15:23'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 2'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:37:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'dcd12a51-6353-41ae-81cd-19e779a5feef'	System	14 Oct 2020 18:43:56
User entered 'Yes (Y)'	System	14 Oct 2020 18:43:56

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:43:40', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'dcd12a51-6353-41ae-81cd-19e779a5feef'	System	14 Oct 2020 18:43:56
User entered '98.2'	System	14 Oct 2020 18:43:56

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:43:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'dcd12a51-6353-41ae-81cd-19e779a5feef'	System	14 Oct 2020 18:43:56
User entered 'No (N)'	System	14 Oct 2020 18:43:56

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:43:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'dcd12a51-6353-41ae-81cd-19e779a5feef'	System	14 Oct 2020 18:43:56
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:56

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 3'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:58:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '366f6ddc-47df-4be4-a45f-5fbe95d1e3b7'	System	16 Oct 2020 00:59:03
User entered 'Yes (Y)'	System	16 Oct 2020 00:59:03

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:58:42', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '366f6ddc-47df-4be4-a45f-5fbe95d1e3b7'	System	16 Oct 2020 00:59:03
User entered '98.6'	System	16 Oct 2020 00:59:03

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:58:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '366f6ddc-47df-4be4-a45f-5fbe95d1e3b7'	System	16 Oct 2020 00:59:03
User entered 'No (N)'	System	16 Oct 2020 00:59:03

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:58:55', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '366f6ddc-47df-4be4-a45f-5fbe95d1e3b7'	System	16 Oct 2020 00:59:03
User entered '15 Oct 2020 19:58'	System	16 Oct 2020 00:59:03

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 4'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:29:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ead3c714-9a9b-4ca2-9e92-5dafcb9f99aa'	System	17 Oct 2020 15:30:06
User entered 'Yes (Y)'	System	17 Oct 2020 15:30:06

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:29:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ead3c714-9a9b-4ca2-9e92-5dafcb9f99aa'	System	17 Oct 2020 15:30:06
User entered '98.6'	System	17 Oct 2020 15:30:06

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:29:58', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ead3c714-9a9b-4ca2-9e92-5dafcb9f99aa'	System	17 Oct 2020 15:30:06
User entered 'No (N)'	System	17 Oct 2020 15:30:06

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ead3c714-9a9b-4ca2-9e92-5dafcb9f99aa'	System	17 Oct 2020 15:30:06
User entered '17 Oct 2020 10:30'	System	17 Oct 2020 15:30:06

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 5'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:49:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fc1cca72-f495-40fc-93ed-d38792514404'	System	18 Oct 2020 00:49:57
User entered 'Yes (Y)'	System	18 Oct 2020 00:49:57

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:49:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fc1cca72-f495-40fc-93ed-d38792514404'	System	18 Oct 2020 00:49:57
User entered '98.6'	System	18 Oct 2020 00:49:57

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:49:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fc1cca72-f495-40fc-93ed-d38792514404'	System	18 Oct 2020 00:49:57
User entered 'No (N)'	System	18 Oct 2020 00:49:57

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:49:53', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fc1cca72-f495-40fc-93ed-d38792514404'	System	18 Oct 2020 00:49:57
User entered '17 Oct 2020 19:49'	System	18 Oct 2020 00:49:57

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 6'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:22:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fdc18dc5-76a8-4a4b-8cbf-bc8b2f349004'	System	19 Oct 2020 04:23:10
User entered 'Yes (Y)'	System	19 Oct 2020 04:23:10



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:22:59', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fdc18dc5-76a8-4a4b-8cbf-bc8b2f349004'	System	19 Oct 2020 04:23:10
User entered '98.6'	System	19 Oct 2020 04:23:10

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fdc18dc5-76a8-4a4b-8cbf-bc8b2f349004'	System	19 Oct 2020 04:23:10
User entered 'No (N)'	System	19 Oct 2020 04:23:10

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:08', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fdc18dc5-76a8-4a4b-8cbf-bc8b2f349004'	System	19 Oct 2020 04:23:10
User entered '18 Oct 2020 23:23'	System	19 Oct 2020 04:23:10

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 7'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40



US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '3b264823-0921-4d60-9509-64bbd4d0dd29'	System	13 Oct 2020 17:19:42
User entered 'None (1)'	System	13 Oct 2020 17:19:42



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '3b264823-0921-4d60-9509-64bbd4d0dd29'	System	13 Oct 2020 17:19:42
User entered 'No (N)'	System	13 Oct 2020 17:19:42

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:22', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '3b264823-0921-4d60-9509-64bbd4d0dd29'	System	13 Oct 2020 17:19:42
User entered 'No (N)'	System	13 Oct 2020 17:19:42

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:31', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '3b264823-0921-4d60-9509-64bbd4d0dd29'	System	13 Oct 2020 17:19:42
User entered 'None (1)'	System	13 Oct 2020 17:19:42

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:36', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '3b264823-0921-4d60-9509-64bbd4d0dd29'	System	13 Oct 2020 17:19:42
User entered '13 Oct 2020 12:19'	System	13 Oct 2020 17:19:42

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 11:58'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 14:28'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '8c7e9f1e-25e1-471c-857a-45f917d949f8'	System	13 Oct 2020 20:29:50
User entered 'None (1)'	System	13 Oct 2020 20:29:50



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '8c7e9f1e-25e1-471c-857a-45f917d949f8'	System	13 Oct 2020 20:29:50
User entered 'No (N)'	System	13 Oct 2020 20:29:50

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:36', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '8c7e9f1e-25e1-471c-857a-45f917d949f8'	System	13 Oct 2020 20:29:50
User entered 'No (N)'	System	13 Oct 2020 20:29:50

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:41', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '8c7e9f1e-25e1-471c-857a-45f917d949f8'	System	13 Oct 2020 20:29:50
User entered 'None (1)'	System	13 Oct 2020 20:29:50

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:29:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '8c7e9f1e-25e1-471c-857a-45f917d949f8'	System	13 Oct 2020 20:29:50
User entered '13 Oct 2020 15:29'	System	13 Oct 2020 20:29:50

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 15:23'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 2'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ebc83c7a-059d-48c0-9246-47a92e5ed4ea'	System	14 Oct 2020 18:44:26
User entered 'None (1)'	System	14 Oct 2020 18:44:26



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ebc83c7a-059d-48c0-9246-47a92e5ed4ea'	System	14 Oct 2020 18:44:26
User entered 'No (N)'	System	14 Oct 2020 18:44:26

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:12', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ebc83c7a-059d-48c0-9246-47a92e5ed4ea'	System	14 Oct 2020 18:44:26
User entered 'No (N)'	System	14 Oct 2020 18:44:26

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ebc83c7a-059d-48c0-9246-47a92e5ed4ea'	System	14 Oct 2020 18:44:26
User entered 'None (1)'	System	14 Oct 2020 18:44:26

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:22', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ebc83c7a-059d-48c0-9246-47a92e5ed4ea'	System	14 Oct 2020 18:44:26
User entered '14 Oct 2020 13:44'	System	14 Oct 2020 18:44:26

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 3'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '90bfe0e1-11fb-4960-99e1-32c78e1e8581'	System	16 Oct 2020 00:59:29
User entered 'None (1)'	System	16 Oct 2020 00:59:29



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '90bfe0e1-11fb-4960-99e1-32c78e1e8581'	System	16 Oct 2020 00:59:29
User entered 'No (N)'	System	16 Oct 2020 00:59:29

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '90bfe0e1-11fb-4960-99e1-32c78e1e8581'	System	16 Oct 2020 00:59:29
User entered 'No (N)'	System	16 Oct 2020 00:59:29

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '90bfe0e1-11fb-4960-99e1-32c78e1e8581'	System	16 Oct 2020 00:59:29
User entered 'None (1)'	System	16 Oct 2020 00:59:29

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:22', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '90bfe0e1-11fb-4960-99e1-32c78e1e8581'	System	16 Oct 2020 00:59:29
User entered '15 Oct 2020 19:59'	System	16 Oct 2020 00:59:29

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 4'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:08', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '323ed0a2-1e88-4c30-80d7-83ebd1001abc'	System	17 Oct 2020 15:30:32
User entered 'None (1)'	System	17 Oct 2020 15:30:32



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '323ed0a2-1e88-4c30-80d7-83ebd1001abc'	System	17 Oct 2020 15:30:32
User entered 'No (N)'	System	17 Oct 2020 15:30:32

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:20', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '323ed0a2-1e88-4c30-80d7-83ebd1001abc'	System	17 Oct 2020 15:30:32
User entered 'No (N)'	System	17 Oct 2020 15:30:32

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:24', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '323ed0a2-1e88-4c30-80d7-83ebd1001abc'	System	17 Oct 2020 15:30:32
User entered 'None (1)'	System	17 Oct 2020 15:30:32

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:27', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '323ed0a2-1e88-4c30-80d7-83ebd1001abc'	System	17 Oct 2020 15:30:32
User entered '17 Oct 2020 10:30'	System	17 Oct 2020 15:30:32

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 5'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '23ecfb62-6e29-4585-8626-fa4e1ea65a70'	System	18 Oct 2020 00:50:24
User entered 'None (1)'	System	18 Oct 2020 00:50:24



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '23ecfb62-6e29-4585-8626-fa4e1ea65a70'	System	18 Oct 2020 00:50:24
User entered 'No (N)'	System	18 Oct 2020 00:50:24

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '23ecfb62-6e29-4585-8626-fa4e1ea65a70'	System	18 Oct 2020 00:50:24
User entered 'No (N)'	System	18 Oct 2020 00:50:24

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '23ecfb62-6e29-4585-8626-fa4e1ea65a70'	System	18 Oct 2020 00:50:24
User entered 'None (1)'	System	18 Oct 2020 00:50:24

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:17', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '23ecfb62-6e29-4585-8626-fa4e1ea65a70'	System	18 Oct 2020 00:50:24
User entered '17 Oct 2020 19:50'	System	18 Oct 2020 00:50:24

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 6'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6ff6b5b0-1da9-47e1-a489-202fde6a76de'	System	19 Oct 2020 04:23:37
User entered 'None (1)'	System	19 Oct 2020 04:23:37



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:19', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6ff6b5b0-1da9-47e1-a489-202fde6a76de'	System	19 Oct 2020 04:23:37
User entered 'No (N)'	System	19 Oct 2020 04:23:37

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6ff6b5b0-1da9-47e1-a489-202fde6a76de'	System	19 Oct 2020 04:23:37
User entered 'No (N)'	System	19 Oct 2020 04:23:37

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6ff6b5b0-1da9-47e1-a489-202fde6a76de'	System	19 Oct 2020 04:23:37
User entered 'None (1)'	System	19 Oct 2020 04:23:37

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6ff6b5b0-1da9-47e1-a489-202fde6a76de'	System	19 Oct 2020 04:23:37
User entered '18 Oct 2020 23:23'	System	19 Oct 2020 04:23:37

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 7'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40



US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:19:55', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:20:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:20:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:20:08', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'None (0)'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:20:27', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered 'No (N)'	System	13 Oct 2020 17:20:46



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T12:20:41', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6aa36776-e122-47f9-95bd-b15a4b701ac5'	System	13 Oct 2020 17:20:46
User entered '13 Oct 2020 12:20'	System	13 Oct 2020 17:20:46

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 11:58'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 14:28'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:02', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:21', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:26', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:30', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'None (0)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:39', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered 'No (N)'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-13T15:30:46', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '65a487f1-820c-48fc-8cf7-8838dfd8583a'	System	13 Oct 2020 20:30:51
User entered '13 Oct 2020 15:30'	System	13 Oct 2020 20:30:51

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Oct 2020 15:23'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 2'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:30', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:37', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:53', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:44:57', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:45:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'None (0)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:45:11', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered 'No (N)'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-14T13:45:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f7ca22dc-913a-4580-ba75-fab5b40ad9a3'	System	14 Oct 2020 18:45:20
User entered '14 Oct 2020 13:45'	System	14 Oct 2020 18:45:20

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 3'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T19:59:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'None (0)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:03:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'Some interference with activity (2)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:02:53', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'None (0)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:02:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'None (0)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:05:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'None (0)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:05:47', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeeb-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'None (0)'	System	16 Oct 2020 01:06:12



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:05:54', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeeb-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered 'No (N)'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-15T20:06:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f208a0a0-f3f6-495e-aeab-2e1d28bbb72c'	System	16 Oct 2020 01:06:12
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 01:06:12

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 4'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:33', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:36', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:40', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:49', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'None (0)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:30:58', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered 'No (N)'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T10:31:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '22a61678-81f3-4cc1-b908-4d61615d8bad'	System	17 Oct 2020 15:31:05
User entered '17 Oct 2020 10:31'	System	17 Oct 2020 15:31:05

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 5'	System	13 Oct 2020 16:55:43



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:26', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:29', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:35', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'None (0)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered 'No (N)'	System	18 Oct 2020 00:50:58

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-17T19:50:55', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1a366e29-cb40-4466-a0bc-3c7a6559b7a0'	System	18 Oct 2020 00:50:58
User entered '17 Oct 2020 19:50'	System	18 Oct 2020 00:50:58



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 6'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:41', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:55', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:23:59', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:24:02', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'None (0)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:24:09', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered 'No (N)'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-10-18T23:24:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ae513ede-e076-45b2-8cbe-68a9b53c6372'	System	19 Oct 2020 04:24:16
User entered '18 Oct 2020 23:24'	System	19 Oct 2020 04:24:16

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	13 Oct 2020 16:55:43
User entered 'Day 7'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40



US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:55:43

US3342354

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:55:43



US3342354

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:02:24

US3342354

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:02:24

US3342354

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:02:24

US3342354

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:02:24

US3342354

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:02:30

US3342354

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered 'I'	System	20 Oct 2020 22:02:30

**US3342354**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Oct 2020 16:41:28

US3342354

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '27 Oct 2020'	Ethan Shotton (b) (4)	27 Oct 2020 16:41:28



US3342354

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	27 Oct 2020 16:41:28

US3342354

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 16:41:28

US3342354

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:05:26

US3342354

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:21:11
User entered '1'	System	03 Nov 2020 21:05:26

US3342354

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:05:34

US3342354

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:06:05
User entered '3 Nov 2020'	Morgan Schulle (b) (4)	03 Nov 2020 21:05:34
	(b) (4)	

US3342354

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:05:34

US3342354

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:05:34



US3342354

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	03 Nov 2020 21:05:39

US3342354

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:02:22
User entered 'I'	System	03 Nov 2020 21:05:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:28:24

US3342354

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:28:24

US3342354

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[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 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:28:24

US3342354

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'VISIT2'	System	12 Nov 2020 17:28:24

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	12 Nov 2020 18:02:42



US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '10:59'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '12 Nov 2020 10:59'	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '98.7' F	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Oral (Oral)'	(b) (4) Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4)	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	
	(b) (4)	

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '71'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'bpm'	System	12 Nov 2020 18:02:42



US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '16'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'breaths/min'	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '134'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '79'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	12 Nov 2020 18:02:42



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '12:24' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	System	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '12 Nov 2020 12:24'	System	12 Nov 2020 18:28:03
User entered empty.	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '98.7' F reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	System	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 18:28:03
User entered empty.	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) Morgan Schulle (b) (4)	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '65' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	System	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'bpm'	System	12 Nov 2020 18:28:03
User entered empty.	System	12 Nov 2020 18:02:42



US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '16' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	System	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'breaths/min'	System	12 Nov 2020 18:28:03
User entered empty.	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '135' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	12 Nov 2020 18:28:03
User entered empty.	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:28:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	12 Nov 2020 18:28:03
User entered '70' reason for change: Data Entry Error	Morgan Schulle (b) (4)	12 Nov 2020 18:28:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Nov 2020 18:02:42
User entered empty.	System	12 Nov 2020 18:02:42
	Morgan Schulle (b) (4)	12 Nov 2020 18:02:42
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	12 Nov 2020 18:28:03
User entered empty.	System	12 Nov 2020 18:02:42

US3342354

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Morgan Schulle (b) (4)	12 Nov 2020 18:06:54

US3342354

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	12 Nov 2020 18:06:54



US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'MRNA-1273 OR PLACEBO'	System	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:50'	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06

**US3342354**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:09:30**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '12 Nov 2020 11:50'	System	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Left Arm (LEFT ARM)'	Morgan Schulle (b) (4)	12 Nov 2020 18:01:06



US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'ONCE'	System	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'INTRAMUSCULAR'	System	12 Nov 2020 18:01:06

US3342354

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:22

US3342354

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:22

US3342354

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:33'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:22

US3342354

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '12 Nov 2020 11:33'	System	17 Nov 2020 21:03:22

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12 Nov 2020'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	17 Nov 2020 21:03:39



US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:35'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '12 Nov 2020 11:35'	System	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	Morgan Schulle (b) (4)	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Morgan Schulle (b) (4)	17 Nov 2020 21:03:39

**US3342354**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered empty.	System	17 Nov 2020 21:03:39

US3342354

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:28:41



US3342354

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'I'	System	12 Nov 2020 17:28:41

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:25:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd5877242-a6a7-46ed-b2d9-8e641c1a1236'	System	12 Nov 2020 18:26:19
User entered 'Yes (Y)'	System	12 Nov 2020 18:26:19

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:26:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd5877242-a6a7-46ed-b2d9-8e641c1a1236' User entered '98.7'	System	12 Nov 2020 18:26:19
	System	12 Nov 2020 18:26:19

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:26:08', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd5877242-a6a7-46ed-b2d9-8e641c1a1236'	System	12 Nov 2020 18:26:19
User entered 'No (N)'	System	12 Nov 2020 18:26:19

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:26:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd5877242-a6a7-46ed-b2d9-8e641c1a1236'	System	12 Nov 2020 18:26:19
User entered '12 Nov 2020 12:26'	System	12 Nov 2020 18:26:19

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 12:10'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 14:40'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:08:02', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '883cc505-d5ee-4c76-b1a4-69b363ed260d'	System	13 Nov 2020 02:11:10
User entered 'Yes (Y)'	System	13 Nov 2020 02:11:10

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:09:42', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '883cc505-d5ee-4c76-b1a4-69b363ed260d' User entered '97.9'	System	13 Nov 2020 02:11:10
	System	13 Nov 2020 02:11:10

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:09:49', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '883cc505-d5ee-4c76-b1a4-69b363ed260d'	System	13 Nov 2020 02:11:10
User entered 'No (N)'	System	13 Nov 2020 02:11:10

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:11:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '883cc505-d5ee-4c76-b1a4-69b363ed260d'	System	13 Nov 2020 02:11:10
User entered '12 Nov 2020 20:11'	System	13 Nov 2020 02:11:10

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 15:35'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 2'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:05:08', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7d8ceac2-b985-4f25-bea9-6556744a24dd'	System	13 Nov 2020 20:08:11
User entered 'Yes (Y)'	System	13 Nov 2020 20:08:11

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:07:56', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7d8ceac2-b985-4f25-bea9-6556744a24dd'	System	13 Nov 2020 20:08:11
User entered '98.1'	System	13 Nov 2020 20:08:11

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:08:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7d8ceac2-b985-4f25-bea9-6556744a24dd'	System	13 Nov 2020 20:08:11
User entered 'No (N)'	System	13 Nov 2020 20:08:11

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:08:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7d8ceac2-b985-4f25-bea9-6556744a24dd'	System	13 Nov 2020 20:08:11
User entered '13 Nov 2020 14:08'	System	13 Nov 2020 20:08:11

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 3'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:29:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered 'Yes (Y)'	System	15 Nov 2020 00:32:56



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:32:09', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered '98.5'	System	15 Nov 2020 00:32:56

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:32:20', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered 'Yes (Y)'	System	15 Nov 2020 00:32:56

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
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 'Medication has been recorded.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 14:08:36
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).	Olivia Hapanowicz (b) (4)	23 Nov 2020 19:50:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:32:46', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered '1'	System	15 Nov 2020 00:32:56

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:32:46', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered '0'	System	15 Nov 2020 00:32:56

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:32:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '42d4e5f2-d461-4061-8da7-8c62d5c55f1e'	System	15 Nov 2020 00:32:56
User entered '14 Nov 2020 18:32'	System	15 Nov 2020 00:32:56

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 4'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:30:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '4cdcd5a0-ac48-4562-965c-75f6c9015f4a'	System	15 Nov 2020 23:35:43
User entered 'Yes (Y)'	System	15 Nov 2020 23:35:43

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:35:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '4cdcd5a0-ac48-4562-965c-75f6c9015f4a' User entered '98.3'	System	15 Nov 2020 23:35:43
	System	15 Nov 2020 23:35:43

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:35:37', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '4cdcd5a0-ac48-4562-965c-75f6c9015f4a'	System	15 Nov 2020 23:35:43
User entered 'No (N)'	System	15 Nov 2020 23:35:43

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:35:40', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '4cdcd5a0-ac48-4562-965c-75f6c9015f4a'	System	15 Nov 2020 23:35:43
User entered '15 Nov 2020 17:35'	System	15 Nov 2020 23:35:43

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 5'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:30', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '26ce5146-32af-46d8-8cb2-7e72cfda0c48'	System	17 Nov 2020 04:11:54
User entered 'Yes (Y)'	System	17 Nov 2020 04:11:54



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '26ce5146-32af-46d8-8cb2-7e72cfda0c48'	System	17 Nov 2020 04:11:54
User entered '94.2'	System	17 Nov 2020 04:11:54

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:49', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '26ce5146-32af-46d8-8cb2-7e72cfda0c48'	System	17 Nov 2020 04:11:54
User entered 'No (N)'	System	17 Nov 2020 04:11:54

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '26ce5146-32af-46d8-8cb2-7e72cfda0c48'	System	17 Nov 2020 04:11:54
User entered '16 Nov 2020 22:11'	System	17 Nov 2020 04:11:54

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 6'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cf4ac9c6-853d-4e5c-a689-a4b24ec1990a'	System	18 Nov 2020 05:09:16
User entered 'Yes (Y)'	System	18 Nov 2020 05:09:16

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:09:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cf4ac9c6-853d-4e5c-a689-a4b24ec1990a'	System	18 Nov 2020 05:09:16
User entered '97.2'	System	18 Nov 2020 05:09:16



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:09:11', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cf4ac9c6-853d-4e5c-a689-a4b24ec1990a'	System	18 Nov 2020 05:09:16
User entered 'No (N)'	System	18 Nov 2020 05:09:16

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:09:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cf4ac9c6-853d-4e5c-a689-a4b24ec1990a'	System	18 Nov 2020 05:09:16
User entered '17 Nov 2020 23:09'	System	18 Nov 2020 05:09:16

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 7'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:01:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'bd9bcb5d-4a79-474a-a507-9217d29c8e2d'	System	19 Nov 2020 06:01:23
User entered 'Yes (Y)'	System	19 Nov 2020 06:01:23

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:01:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'bd9bcb5d-4a79-474a-a507-9217d29c8e2d' User entered '97.4'	System	19 Nov 2020 06:01:23
	System	19 Nov 2020 06:01:23

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:01:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'bd9bcb5d-4a79-474a-a507-9217d29c8e2d'	System	19 Nov 2020 06:01:23
User entered 'No (N)'	System	19 Nov 2020 06:01:23



US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:01:20', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'bd9bcb5d-4a79-474a-a507-9217d29c8e2d'	System	19 Nov 2020 06:01:23
User entered '19 Nov 2020 00:01'	System	19 Nov 2020 06:01:23

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:23:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '564b7696-e665-4ad6-bd62-f615e4801ea5'	System	12 Nov 2020 18:23:52
User entered 'None (1)'	System	12 Nov 2020 18:23:52

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:23:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '564b7696-e665-4ad6-bd62-f615e4801ea5'	System	12 Nov 2020 18:23:52
User entered 'No (N)'	System	12 Nov 2020 18:23:52

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:23:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '564b7696-e665-4ad6-bd62-f615e4801ea5'	System	12 Nov 2020 18:23:52
User entered 'No (N)'	System	12 Nov 2020 18:23:52

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:23:42', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '564b7696-e665-4ad6-bd62-f615e4801ea5'	System	12 Nov 2020 18:23:52
User entered 'None (1)'	System	12 Nov 2020 18:23:52



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:23:46', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '564b7696-e665-4ad6-bd62-f615e4801ea5'	System	12 Nov 2020 18:23:52
User entered '12 Nov 2020 12:23'	System	12 Nov 2020 18:23:52

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 12:10'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 14:40'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:06:56', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cec92c6f-67f7-45b0-bc5c-27bc1e16333c'	System	13 Nov 2020 02:07:54
User entered 'None (1)'	System	13 Nov 2020 02:07:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:07:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cec92c6f-67f7-45b0-bc5c-27bc1e16333c'	System	13 Nov 2020 02:07:54
User entered 'No (N)'	System	13 Nov 2020 02:07:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:07:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cec92c6f-67f7-45b0-bc5c-27bc1e16333c'	System	13 Nov 2020 02:07:54
User entered 'No (N)'	System	13 Nov 2020 02:07:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:07:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cec92c6f-67f7-45b0-bc5c-27bc1e16333c'	System	13 Nov 2020 02:07:54
User entered 'None (1)'	System	13 Nov 2020 02:07:54



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:07:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'cec92c6f-67f7-45b0-bc5c-27bc1e16333c'	System	13 Nov 2020 02:07:54
User entered '12 Nov 2020 20:07'	System	13 Nov 2020 02:07:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 15:35'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 2'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:04:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '59a1af86-c63d-4333-bb8a-92566d302ccb'	System	13 Nov 2020 20:04:55
User entered 'None (1)'	System	13 Nov 2020 20:04:55

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:04:29', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '59a1af86-c63d-4333-bb8a-92566d302ccb'	System	13 Nov 2020 20:04:55
User entered 'No (N)'	System	13 Nov 2020 20:04:55

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:04:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '59a1af86-c63d-4333-bb8a-92566d302ccb'	System	13 Nov 2020 20:04:55
User entered 'No (N)'	System	13 Nov 2020 20:04:55

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:04:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '59a1af86-c63d-4333-bb8a-92566d302ccb'	System	13 Nov 2020 20:04:55
User entered 'None (1)'	System	13 Nov 2020 20:04:55



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:04:52', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '59a1af86-c63d-4333-bb8a-92566d302ccb'	System	13 Nov 2020 20:04:55
User entered '13 Nov 2020 14:04'	System	13 Nov 2020 20:04:55

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 3'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:28:33', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5689a2cb-39dd-460d-adb4-1d523868f01a'	System	15 Nov 2020 00:29:31
User entered 'None (1)'	System	15 Nov 2020 00:29:31

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:29:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5689a2cb-39dd-460d-adb4-1d523868f01a'	System	15 Nov 2020 00:29:31
User entered 'No (N)'	System	15 Nov 2020 00:29:31

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:29:20', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5689a2cb-39dd-460d-adb4-1d523868f01a'	System	15 Nov 2020 00:29:31
User entered 'No (N)'	System	15 Nov 2020 00:29:31

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:29:25', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5689a2cb-39dd-460d-adb4-1d523868f01a'	System	15 Nov 2020 00:29:31
User entered 'None (1)'	System	15 Nov 2020 00:29:31



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:29:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5689a2cb-39dd-460d-adb4-1d523868f01a'	System	15 Nov 2020 00:29:31
User entered '14 Nov 2020 18:29'	System	15 Nov 2020 00:29:31

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 4'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:22', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fe08be03-6db0-4fe4-88e6-dacd8180bca6'	System	15 Nov 2020 23:29:40
User entered 'None (1)'	System	15 Nov 2020 23:29:40

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:25', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fe08be03-6db0-4fe4-88e6-dacd8180bca6'	System	15 Nov 2020 23:29:40
User entered 'No (N)'	System	15 Nov 2020 23:29:40

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fe08be03-6db0-4fe4-88e6-dacd8180bca6'	System	15 Nov 2020 23:29:40
User entered 'No (N)'	System	15 Nov 2020 23:29:40

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fe08be03-6db0-4fe4-88e6-dacd8180bca6'	System	15 Nov 2020 23:29:40
User entered 'None (1)'	System	15 Nov 2020 23:29:40



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'fe08be03-6db0-4fe4-88e6-dacd8180bca6'	System	15 Nov 2020 23:29:40
User entered '15 Nov 2020 17:29'	System	15 Nov 2020 23:29:40

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 5'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:03', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '06e859f4-94f5-4aaa-9f80-49b868b347a0'	System	17 Nov 2020 04:11:19
User entered 'None (1)'	System	17 Nov 2020 04:11:19

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '06e859f4-94f5-4aaa-9f80-49b868b347a0'	System	17 Nov 2020 04:11:19
User entered 'No (N)'	System	17 Nov 2020 04:11:19

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '06e859f4-94f5-4aaa-9f80-49b868b347a0'	System	17 Nov 2020 04:11:19
User entered 'No (N)'	System	17 Nov 2020 04:11:19

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:14', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '06e859f4-94f5-4aaa-9f80-49b868b347a0'	System	17 Nov 2020 04:11:19
User entered 'None (1)'	System	17 Nov 2020 04:11:19



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:11:16', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '06e859f4-94f5-4aaa-9f80-49b868b347a0'	System	17 Nov 2020 04:11:19
User entered '16 Nov 2020 22:11'	System	17 Nov 2020 04:11:19

**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 6'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:21', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '07fd7903-6bc2-4531-a68b-742c57bb3004'	System	18 Nov 2020 05:08:36
User entered 'None (1)'	System	18 Nov 2020 05:08:36

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:24', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '07fd7903-6bc2-4531-a68b-742c57bb3004'	System	18 Nov 2020 05:08:36
User entered 'No (N)'	System	18 Nov 2020 05:08:36

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '07fd7903-6bc2-4531-a68b-742c57bb3004'	System	18 Nov 2020 05:08:36
User entered 'No (N)'	System	18 Nov 2020 05:08:36

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:31', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '07fd7903-6bc2-4531-a68b-742c57bb3004'	System	18 Nov 2020 05:08:36
User entered 'None (1)'	System	18 Nov 2020 05:08:36



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '07fd7903-6bc2-4531-a68b-742c57bb3004'	System	18 Nov 2020 05:08:36
User entered '17 Nov 2020 23:08'	System	18 Nov 2020 05:08:36

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 7'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:37', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '847f607b-5d33-4f57-9124-ae61a7cc37ae'	System	19 Nov 2020 06:00:54
User entered 'None (1)'	System	19 Nov 2020 06:00:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:42', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '847f607b-5d33-4f57-9124-ae61a7cc37ae'	System	19 Nov 2020 06:00:54
User entered 'No (N)'	System	19 Nov 2020 06:00:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:45', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '847f607b-5d33-4f57-9124-ae61a7cc37ae'	System	19 Nov 2020 06:00:54
User entered 'No (N)'	System	19 Nov 2020 06:00:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

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 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '847f607b-5d33-4f57-9124-ae61a7cc37ae'	System	19 Nov 2020 06:00:54
User entered 'None (1)'	System	19 Nov 2020 06:00:54



US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '847f607b-5d33-4f57-9124-ae61a7cc37ae'	System	19 Nov 2020 06:00:54
User entered '19 Nov 2020 00:00'	System	19 Nov 2020 06:00:54

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:21', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:27', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:31', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:21:41', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'None (0)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:22:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered 'No (N)'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T12:22:31', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd324c01b-c9fa-4c67-a80e-62a7c158f231'	System	12 Nov 2020 18:22:37
User entered '12 Nov 2020 12:22'	System	12 Nov 2020 18:22:37

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 12:10'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 14:40'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:05:12', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:05:49', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:05:54', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:05:59', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:06:19', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:06:24', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'None (0)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:06:32', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered 'No (N)'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-12T20:06:36', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5603c38b-b5a3-4fdc-bc89-db4c2e472fb7'	System	13 Nov 2020 02:06:41
User entered '12 Nov 2020 20:06'	System	13 Nov 2020 02:06:41

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '12 Nov 2020 15:35'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 2'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:02:31', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'None (0)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:02:35', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'None (0)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:20', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'None (0)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:36', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'No interference with activity (1)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:39', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'None (0)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'None (0)'	System	13 Nov 2020 20:03:54



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:47', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered 'No (N)'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-13T14:03:50', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '12c76282-8199-4b7d-b6b0-3a16fd5729b7'	System	13 Nov 2020 20:03:54
User entered '13 Nov 2020 14:03'	System	13 Nov 2020 20:03:54

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 3'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:27:21', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:27:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'None (0)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:27:53', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'None (0)'	System	15 Nov 2020 00:28:15



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:27:57', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'None (0)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:28:02', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'None (0)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:28:05', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'None (0)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:28:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered 'No (N)'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-14T18:28:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '2da99cfc-6dc2-4a15-b1b0-2b1c106f9505'	System	15 Nov 2020 00:28:15
User entered '14 Nov 2020 18:28'	System	15 Nov 2020 00:28:15

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 4'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:28:40', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'None (0)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:28:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'None (0)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:28:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'None (0)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:28:58', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268' User entered 'None (0)'	System	15 Nov 2020 23:29:12
	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'None (0)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'None (0)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered 'No (N)'	System	15 Nov 2020 23:29:12

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-15T17:29:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'a263153d-8e4c-43a2-bee1-31759143d268'	System	15 Nov 2020 23:29:12
User entered '15 Nov 2020 17:29'	System	15 Nov 2020 23:29:12



**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 5'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:41', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:46', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:48', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:51', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'None (0)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:54', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered 'No (N)'	System	17 Nov 2020 04:11:02

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-16T22:10:57', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '6327daf4-4621-41ed-9217-220f6bc32990'	System	17 Nov 2020 04:11:02
User entered '16 Nov 2020 22:10'	System	17 Nov 2020 04:11:02

**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 6'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:07:56', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:07:58', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:10', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'None (0)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered 'No (N)'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-17T23:08:15', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd52d25af-100e-4e5d-9130-29a73b5cf127'	System	18 Nov 2020 05:08:17
User entered '17 Nov 2020 23:08'	System	18 Nov 2020 05:08:17

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:01:06



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
Data entry locked.	System	12 Nov 2020 18:01:06
User entered 'Day 7'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:03', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:06', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:09', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:13', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:16', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'None (0)'	System	19 Nov 2020 06:00:31

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered 'No (N)'	System	19 Nov 2020 06:00:31



US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-11-19T00:00:25', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '054ce17e-3ca3-4e02-b3b1-a841cfe350ec'	System	19 Nov 2020 06:00:31
User entered '19 Nov 2020 00:00'	System	19 Nov 2020 06:00:31

**US3342354**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:09:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:01:06

US3342354

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:11:40
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:01:06

US3342354

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:16

US3342354

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:16

US3342354

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:16

US3342354

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:16

US3342354

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:08:21



US3342354

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'I'	System	19 Nov 2020 21:08:21

US3342354

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Dec 2020 20:43:12

US3342354

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '27 Nov 2020'	Eileen Euperio (b) (4)	02 Dec 2020 20:43:12

US3342354

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4)	02 Dec 2020 20:43:12

US3342354

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	Eileen Euperio (b) (4)	02 Dec 2020 20:43:12

US3342354

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Dec 2020 20:42:55

US3342354

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'I'	System	02 Dec 2020 20:42:55

US3342354

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10



US3342354

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10

US3342354

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10

US3342354

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10

US3342354

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:14

US3342354

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'I'	System	03 Dec 2020 17:46:14

US3342354

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09DEC020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09DEC020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' answered with 'this has been updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 07:53:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09DEC020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	Olivia Hapanowicz (b) (4)	19 Jan 2021 22:34:04
User entered 'Yes (Y)'	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09DEC020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:10:32
User entered 'Yes (Y)'	John Luna (b) (4)	10 Dec 2020 19:39:48

US3342354

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '9 Dec 2020'	John Luna (b) (4)	10 Dec 2020 19:39:48

US3342354

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[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 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Clinic (Clinic)'	John Luna (b) (4)	10 Dec 2020 19:39:48



**US3342354**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'VISIT3'	System	10 Dec 2020 19:39:48

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '9 Dec 2020'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '11:57'	John Luna (b) (4)	10 Dec 2020 19:40:25

**US3342354**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '9 Dec 2020 11:57'	System	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '98.1' F	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Oral (Oral)'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	John Luna (b) (4)	10 Dec 2020 19:40:25



US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '77'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'bpm'	System	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'breaths/min'	System	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '149'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '79'	John Luna (b) (4)	10 Dec 2020 19:40:25

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'mmHg'	System	10 Dec 2020 19:40:25



US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08

US3342354

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08

US3342354

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'No (N)'	John Luna (b) (4)	10 Dec 2020 19:40:32

US3342354

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered empty.	John Luna (b) (4)	10 Dec 2020 19:40:32

US3342354

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:24:27

US3342354

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:24:27

US3342354

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered '12:25'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:24:27

**US3342354**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '9 Dec 2020 12:25'	System	23 Dec 2020 20:24:27



US3342354

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Feb 2021 00:07:56
User entered 'Yes (Y)'	John Luna (b) (4)	10 Dec 2020 19:40:40

**US3342354**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered '1'	System	10 Dec 2020 19:40:40

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:12:59', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de'	System	13 Dec 2020 21:13:34
User entered 'Yes (Y)'	System	13 Dec 2020 21:13:34

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:10:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de'	System	13 Dec 2020 21:13:34
User entered 'No (N)'	System	13 Dec 2020 21:13:34

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:10:29', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de'	System	13 Dec 2020 21:13:34
User entered 'No (N)'	System	13 Dec 2020 21:13:34

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:11:04', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de'	System	13 Dec 2020 21:13:34
User entered 'Yes (Y)'	System	13 Dec 2020 21:13:34

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:11:25', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de'	System	13 Dec 2020 21:13:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 21:13:34



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-13T15:13:21', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '5c66c2aa-96ee-4ce9-b0d0-52484f9b64de' User entered '13 Dec 2020 15:13:21'	System	13 Dec 2020 21:13:34
	System	13 Dec 2020 21:13:34

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-21T07:15:01', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ac89e308-8da8-454b-8acf-9fa995982017'	System	21 Dec 2020 13:15:31
User entered 'No (N)'	System	21 Dec 2020 13:15:31

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-21T07:15:18', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ac89e308-8da8-454b-8acf-9fa995982017'	System	21 Dec 2020 13:15:31
User entered 'No (N)'	System	21 Dec 2020 13:15:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-21T07:15:26', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ac89e308-8da8-454b-8acf-9fa995982017'	System	21 Dec 2020 13:15:31
User entered '21 Dec 2020 07:15:26'	System	21 Dec 2020 13:15:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-28T16:15:44', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '9781a7fc-88f3-4cff-9539-be27e317e967'	System	28 Dec 2020 22:16:14
User entered 'No (N)'	System	28 Dec 2020 22:16:14

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-28T16:15:59', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '9781a7fc-88f3-4cff-9539-be27e317e967'	System	28 Dec 2020 22:16:14
User entered 'No (N)'	System	28 Dec 2020 22:16:14

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-28T16:16:11', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '9781a7fc-88f3-4cff-9539-be27e317e967'	System	28 Dec 2020 22:16:14
User entered '28 Dec 2020 16:16:11'	System	28 Dec 2020 22:16:14

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-31T15:31:55', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd47279a5-6084-488f-9f55-dbdd6c447c2c'	System	31 Dec 2020 21:32:13
User entered 'No (N)'	System	31 Dec 2020 21:32:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-31T15:32:07', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd47279a5-6084-488f-9f55-dbdd6c447c2c'	System	31 Dec 2020 21:32:13
User entered 'No (N)'	System	31 Dec 2020 21:32:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2020-12-31T15:32:11', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd47279a5-6084-488f-9f55-dbdd6c447c2c'	System	31 Dec 2020 21:32:13
User entered '31 Dec 2020 15:32:11'	System	31 Dec 2020 21:32:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-07T23:54:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7ce170cb-d736-4f1c-81e5-b7e5f3feaa99'	System	08 Jan 2021 05:54:47
User entered 'No (N)'	System	08 Jan 2021 05:54:47

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-07T23:54:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7ce170cb-d736-4f1c-81e5-b7e5f3feaa99'	System	08 Jan 2021 05:54:47
User entered 'No (N)'	System	08 Jan 2021 05:54:47



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-07T23:54:43', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '7ce170cb-d736-4f1c-81e5-b7e5f3feaa99'	System	08 Jan 2021 05:54:47
User entered '07 Jan 2021 23:54:43'	System	08 Jan 2021 05:54:47

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-21T14:08:23', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f6aa44b0-335f-40bb-9345-ddad28ca9936'	System	21 Jan 2021 20:08:42
User entered 'No (N)'	System	21 Jan 2021 20:08:42



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-21T14:08:30', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f6aa44b0-335f-40bb-9345-ddad28ca9936'	System	21 Jan 2021 20:08:42
User entered 'No (N)'	System	21 Jan 2021 20:08:42

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-21T14:08:34', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f6aa44b0-335f-40bb-9345-ddad28ca9936'	System	21 Jan 2021 20:08:42
User entered '21 Jan 2021 14:08:34'	System	21 Jan 2021 20:08:42

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-29T07:03:27', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '74c3b2bc-50da-412a-96be-e2ffe0b9a29f'	System	29 Jan 2021 13:03:50
User entered 'No (N)'	System	29 Jan 2021 13:03:50

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-29T07:03:40', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '74c3b2bc-50da-412a-96be-e2ffe0b9a29f'	System	29 Jan 2021 13:03:50
User entered 'No (N)'	System	29 Jan 2021 13:03:50

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-01-29T07:03:47', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '74c3b2bc-50da-412a-96be-e2ffe0b9a29f' User entered '29 Jan 2021 07:03:47'	System	29 Jan 2021 13:03:50
	System	29 Jan 2021 13:03:50



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-04T15:21:16', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f9296193-2320-4892-a8b4-098e73433f46'	System	04 Feb 2021 21:21:31
User entered 'No (N)'	System	04 Feb 2021 21:21:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-04T15:21:22', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f9296193-2320-4892-a8b4-098e73433f46'	System	04 Feb 2021 21:21:31
User entered 'No (N)'	System	04 Feb 2021 21:21:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-04T15:21:26', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'f9296193-2320-4892-a8b4-098e73433f46'	System	04 Feb 2021 21:21:31
User entered '04 Feb 2021 15:21:26'	System	04 Feb 2021 21:21:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-11T08:18:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '88776dbc-cc75-4e53-8933-1b32877c64b4'	System	11 Feb 2021 14:18:42
User entered 'No (N)'	System	11 Feb 2021 14:18:42

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-11T08:18:35', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '88776dbc-cc75-4e53-8933-1b32877c64b4'	System	11 Feb 2021 14:18:42
User entered 'No (N)'	System	11 Feb 2021 14:18:42

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (16b5fd8484122d29)', Time: '2021-02-11T08:18:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '88776dbc-cc75-4e53-8933-1b32877c64b4'	System	11 Feb 2021 14:18:42
User entered '11 Feb 2021 08:18:38'	System	11 Feb 2021 14:18:42

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-22T08:34:24', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e844a622-fb1e-40fb-a6ae-f95b51951050'	System	22 Feb 2021 14:34:38
User entered 'No (N)'	System	22 Feb 2021 14:34:38



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-22T08:34:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e844a622-fb1e-40fb-a6ae-f95b51951050'	System	22 Feb 2021 14:34:38
User entered 'No (N)'	System	22 Feb 2021 14:34:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-22T08:34:33', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'e844a622-fb1e-40fb-a6ae-f95b51951050'	System	22 Feb 2021 14:34:38
User entered '22 Feb 2021 08:34:33'	System	22 Feb 2021 14:34:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-25T00:46:28', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '745af16f-d6c5-4bab-8522-0c20627b6d58'	System	25 Feb 2021 06:46:47
User entered 'No (N)'	System	25 Feb 2021 06:46:47

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-25T00:46:33', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '745af16f-d6c5-4bab-8522-0c20627b6d58'	System	25 Feb 2021 06:46:47
User entered 'No (N)'	System	25 Feb 2021 06:46:47

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b13e25f84face5e7)', Time: '2021-02-25T00:46:38', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '745af16f-d6c5-4bab-8522-0c20627b6d58'	System	25 Feb 2021 06:46:47
User entered '25 Feb 2021 00:46:38'	System	25 Feb 2021 06:46:47



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-13T15:53:12-06:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ff1b8921-cb93-4021-aae4-356444abedae'	System	13 Mar 2021 21:53:31
User entered 'No (N)'	System	13 Mar 2021 21:53:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-13T15:53:18-06:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ff1b8921-cb93-4021-aae4-356444abedae'	System	13 Mar 2021 21:53:31
User entered 'No (N)'	System	13 Mar 2021 21:53:31



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-13T15:53:25-06:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ff1b8921-cb93-4021-aae4-356444abedae' User entered '13 Mar 2021 15:53:25'	System	13 Mar 2021 21:53:31
	System	13 Mar 2021 21:53:31

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-19T18:19:07-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0f694504-1eaa-4e4e-b666-164bb9ea2c84'	System	19 Mar 2021 23:19:23
User entered 'No (N)'	System	19 Mar 2021 23:19:23

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-19T18:19:15-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0f694504-1eaa-4e4e-b666-164bb9ea2c84'	System	19 Mar 2021 23:19:23
User entered 'No (N)'	System	19 Mar 2021 23:19:23

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-19T18:19:21-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0f694504-1eaa-4e4e-b666-164bb9ea2c84'	System	19 Mar 2021 23:19:23
User entered '19 Mar 2021 18:19:21'	System	19 Mar 2021 23:19:23

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-25T08:00:38-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '85e3b63e-6a53-4cc3-a089-782b03ad50cf' User entered 'No (N)'	System	25 Mar 2021 13:00:54
	System	25 Mar 2021 13:00:54

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-25T08:00:43-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '85e3b63e-6a53-4cc3-a089-782b03ad50cf'	System	25 Mar 2021 13:00:54
User entered 'No (N)'	System	25 Mar 2021 13:00:54

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-25T08:00:48-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '85e3b63e-6a53-4cc3-a089-782b03ad50cf' User entered '25 Mar 2021 08:00:48'	System	25 Mar 2021 13:00:54
	System	25 Mar 2021 13:00:54

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-02T02:21:31-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ec2ad008-c73c-4bb3-84a7-eeedbeb510e9'	System	02 Apr 2021 07:21:44
User entered 'No (N)'	System	02 Apr 2021 07:21:44

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-02T02:21:36-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ec2ad008-c73c-4bb3-84a7-eeedbeb510e9'	System	02 Apr 2021 07:21:44
User entered 'No (N)'	System	02 Apr 2021 07:21:44

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-02T02:21:40-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'ec2ad008-c73c-4bb3-84a7-eeedbeb510e9'	System	02 Apr 2021 07:21:44
User entered '02 Apr 2021 02:21:40'	System	02 Apr 2021 07:21:44

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-09T01:11:12-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd122599a-e184-4250-9f6d-aa8db4fcf87d'	System	09 Apr 2021 06:11:28
User entered 'No (N)'	System	09 Apr 2021 06:11:28

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-09T01:11:18-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd122599a-e184-4250-9f6d-aa8db4fcf87d'	System	09 Apr 2021 06:11:28
User entered 'No (N)'	System	09 Apr 2021 06:11:28



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-09T01:11:22-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: 'd122599a-e184-4250-9f6d-aa8db4fcf87d'	System	09 Apr 2021 06:11:28
User entered '09 Apr 2021 01:11:22'	System	09 Apr 2021 06:11:28

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-16T17:03:21-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '21d0ca0f-79b8-404f-897c-32bc3d9d5374'	System	16 Apr 2021 22:06:49
User entered 'No (N)'	System	16 Apr 2021 22:06:49

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-16T17:03:26-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '21d0ca0f-79b8-404f-897c-32bc3d9d5374'	System	16 Apr 2021 22:06:49
User entered 'No (N)'	System	16 Apr 2021 22:06:49

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-16T17:03:29-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '21d0ca0f-79b8-404f-897c-32bc3d9d5374'	System	16 Apr 2021 22:06:49
User entered '16 Apr 2021 17:03:29'	System	16 Apr 2021 22:06:49

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-22T11:43:59-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0b07d011-f1d6-4072-8327-a296583d4cea' User entered 'No (N)'	System	22 Apr 2021 16:44:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-22T11:44:05-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0b07d011-f1d6-4072-8327-a296583d4cea'	System	22 Apr 2021 16:44:13
User entered 'No (N)'	System	22 Apr 2021 16:44:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-22T11:44:08-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '0b07d011-f1d6-4072-8327-a296583d4cea'	System	22 Apr 2021 16:44:13
User entered '22 Apr 2021 11:44:08'	System	22 Apr 2021 16:44:13

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:04:26-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered 'Yes (Y)'	System	29 Apr 2021 14:05:38

US3342354

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:04:33-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered 'No (N)'	System	29 Apr 2021 14:05:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:04:42-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered 'No (N)'	System	29 Apr 2021 14:05:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:04:53-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered 'Yes (Y)'	System	29 Apr 2021 14:05:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:05:19-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 14:05:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-04-29T09:05:25-05:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '52724867-0de4-495e-a2bc-0a0c79320d48'	System	29 Apr 2021 14:05:38
User entered '29 Apr 2021 09:05:25'	System	29 Apr 2021 14:05:38

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 12:04:25



**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '08 Dec 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '12 Dec 2022 23:59'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '15 Dec 2022 00:01'	System	20 Nov 2020 12:04:25

**US3342354**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:04:25
Amendment Manager: User entered '19 Dec 2022 23:59'	System	20 Nov 2020 12:04:25

US3342354

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:09:30**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-13T15:53:39-06:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1e1823ca-c4f9-4ab5-895a-949858a973c7'	System	13 Mar 2021 21:53:51
User entered 'No (N)'	System	13 Mar 2021 21:53:51



**US3342354**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (91c122aaca4c3c9c)', Time: '2021-03-13T15:53:46-06:00', User OID: 'PatientReportedOutcome (US3342354)', ODM File OID: '1e1823ca-c4f9-4ab5-895a-949858a973c7'	System	13 Mar 2021 21:53:51
User entered '13 Mar 2021 15:53:46'	System	13 Mar 2021 21:53:51

US3342354

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:34:47

US3342354

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:34:47

US3342354

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:34:47

US3342354

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:34:47

US3342354

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:34:53

US3342354

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:00:08
User entered 'I'	System	05 Jan 2021 21:34:53

**US3342354**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 19:46:40



**US3342354**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:31
User entered '01 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 19:46:40

**US3342354**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 19:46:40

US3342354

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 19:46:40

US3342354

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 19:46:44

US3342354

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User entered 'I'	System	01 Feb 2021 19:46:44

US3342354

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:34

US3342354

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:34

US3342354

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:34



US3342354

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:34

US3342354

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:40

US3342354

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:01:42
User entered 'I'	System	09 Mar 2021 22:23:40

**US3342354**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:06:25

US3342354

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:06:25

**US3342354**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:06:25

US3342354

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:06:25

US3342354

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:06:32



**US3342354**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 14:06:32

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:32:58

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '19 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:32:58

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:32:58

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 17:32:58

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '19 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:09:30**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:21:14

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20



**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:09:30**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:21:14

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '19 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Placebo (Placebo)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Placebo (Placebo)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Placebo (Placebo)'	(b) (4) Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	28 Jan 2021 20:47:55
User entered 'No (N)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	28 Jan 2021 20:44:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	28 Jan 2021 20:37:02
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '1'	System	21 Jan 2021 17:33:20

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'I'	System	28 Jan 2021 20:47:55
User entered empty.	System	28 Jan 2021 20:44:57
User entered 'I'	System	28 Jan 2021 20:37:02
User entered empty.	System	21 Jan 2021 17:33:20



US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
DataPoint set to visible.	System	28 Jan 2021 20:47:55
DataPoint set to invisible.	System	28 Jan 2021 20:44:57
User entered empty.	System	28 Jan 2021 20:37:53
DataPoint set to visible.	System	28 Jan 2021 20:37:02

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:09:30**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
DataPoint set to visible.	System	28 Jan 2021 20:47:55
DataPoint set to invisible.	System	28 Jan 2021 20:44:57
User entered empty.	System	28 Jan 2021 20:37:53
DataPoint set to visible.	System	28 Jan 2021 20:37:02

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:17:11
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 20:37:53
User entered '28 Jan 2021'	Morgan Schulle (b) (4) (b) (4)	28 Jan 2021 20:37:53

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:09:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '13:35'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '28 Jan 2021 13:35'	System	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '98.7' F	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Oral (Oral)'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '85'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'bpm'	System	28 Jan 2021 20:37:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '16'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'breaths/min'	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '132'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'mmHg'	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '77'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'mmHg'	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered missing code ND - Not Done.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
DataPoint set to visible.	System	28 Jan 2021 20:47:55
DataPoint set to invisible.	System	28 Jan 2021 20:44:57
User entered empty.	System	28 Jan 2021 20:37:53
DataPoint set to visible.	System	28 Jan 2021 20:37:02

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:17:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 20:37:53
User entered '28 Jan 2021'	Morgan Schulle (b) (4) (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Feb 2021 20:28:06
User entered '14:45' reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '28 Jan 2021 14:45'	System	02 Feb 2021 20:28:06
User entered empty.	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Feb 2021 20:28:06
User entered '98.4' F reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User entered empty.	(b) (4) Morgan Schulle (b) (4)	28 Jan 2021 20:37:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Feb 2021 20:28:06
User entered '73' reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'bpm'	System	02 Feb 2021 20:28:06
User entered empty.	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System	System	02 Feb 2021 20:28:06
data change (Site from System).		
User entered '12' reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'breaths/min'	System	02 Feb 2021 20:28:06
User entered empty.	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System	System	02 Feb 2021 20:28:06
data change (Site from System).		
User entered '145' reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'mmHg'	System	02 Feb 2021 20:28:06
User entered empty.	System	28 Jan 2021 20:37:53

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Feb 2021 20:28:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Feb 2021 20:28:06
User entered '87' reason for change: Data Entry Error	Stefanie Mott (b) (4)	02 Feb 2021 20:28:06
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 20:37:53
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:37:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'mmHg'	System	02 Feb 2021 20:28:06
User entered empty.	System	28 Jan 2021 20:37:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	Morgan Schulle (b) (4)	28 Jan 2021 20:48:00

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:48:00

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Jan 2021 20:48:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:48:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Morgan Schulle (b) (4)	28 Jan 2021 20:48:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'mRNA-1273'	System	28 Jan 2021 20:48:29
DataPoint set to visible.	System	28 Jan 2021 20:47:55

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:13:39
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 20:48:29
User entered '28 Jan 2021'	Morgan Schulle (b) (4) (b) (4)	28 Jan 2021 20:48:29



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '14:14'	Morgan Schulle (b) (4)	28 Jan 2021 20:48:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '28 Jan 2021 14:14'	System	28 Jan 2021 20:48:29

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Left Arm (LEFT ARM)'	Morgan Schulle (b) (4)	28 Jan 2021 20:48:29

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'ONCE'	System	28 Jan 2021 20:48:29

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 20:48:29

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'sample was received, req number 1F619127449' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 11:06:43
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'sample was received, req number 1F619127449' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	12 Feb 2021 17:53:23
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:17:50
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Feb 2021 16:45:42

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:18:53
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'VACCINATION VISIT WAS DELAYED' (Site from System).	Eileen Euperio (b) (4) (b) (4)	02 Feb 2021 16:45:59
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Feb 2021 16:45:42
User entered '28 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	02 Feb 2021 16:45:42

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:30**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '14:02'	Eileen Euperio (b) (4)	02 Feb 2021 16:45:42



US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '28 Jan 2021 14:02'	System	02 Feb 2021 16:45:42

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:09:30**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Feb 2021 16:46:10

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '28 Jan 2021'	Eileen Euperio (b) (4)	02 Feb 2021 16:46:10

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:09:30**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '14:04'	Eileen Euperio (b) (4)	02 Feb 2021 16:46:10

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:09:30**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered '28 Jan 2021 14:04'	System	02 Feb 2021 16:46:10

US3342354

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Jan 2021 20:38:13

**US3342354**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:13:29
User entered 'I'	System	28 Jan 2021 20:38:13

**US3342354**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	10 Feb 2021 21:10:23



US3342354

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:17:39
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD noted.' (Site from System).	Ethan Shotton (b) (4) (b) (4)	23 Feb 2021 16:58:50
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:58:23
User entered '10 Feb 2021'	Ethan Shotton (b) (4) (b) (4)	10 Feb 2021 21:10:23

US3342354

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	10 Feb 2021 21:10:23

US3342354

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Ethan Shotton (b) (4)	10 Feb 2021 21:10:23

US3342354

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	10 Feb 2021 21:20:36

**US3342354**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'I'	System	10 Feb 2021 21:20:36

**US3342354**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered '1'	System	10 Feb 2021 21:20:36
DataPoint set to visible.	System	10 Feb 2021 21:20:36

**US3342354**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Feb 2021 18:51:39

**US3342354**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '26 Feb 2021'	Ethan Shotton (b) (4)	26 Feb 2021 18:51:39



US3342354

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Clinic (Clinic)'	Ethan Shotton (b) (4)	26 Feb 2021 18:51:39

**US3342354**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'OLD29'	System	26 Feb 2021 18:51:39

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User accepted default value 'Pre-Dose (PREDOSE)'	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '26 Feb 2021'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:09:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '11:59'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered '26 Feb 2021 11:59'	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '98.2' F	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56



US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:09:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '84'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'bpm'	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '12'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'breaths/min'	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '139'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'mmHg'	System	26 Feb 2021 18:52:56



US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '82'	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'mmHg'	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User accepted default value 'Post-Dose (POSTDOSE)'	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Feb 2021 20:32:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 20:32:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 20:32:58
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 18:52:56
User entered empty.	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:09:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '13:27' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered '26 Feb 2021 13:27'	System	26 Feb 2021 20:32:58
User entered empty.	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '98.3' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56



US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Ethan Shotton (b) (4)	26 Feb 2021 18:52:56

**US3342354**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '93' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'bpm'	System	26 Feb 2021 20:32:58
User entered empty.	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'breaths/min'	System	26 Feb 2021 20:32:58
User entered empty.	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '147' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'mmHg'	System	26 Feb 2021 20:32:58
User entered empty.	System	26 Feb 2021 18:52:56



US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '87' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:32:58
User entered empty.	Ethan Shotton (b) (4) (b) (4)	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'mmHg'	System	26 Feb 2021 20:32:58
User entered empty.	System	26 Feb 2021 18:52:56

US3342354

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'No (N)'	Ethan Shotton (b) (4)	26 Feb 2021 18:53:02

US3342354

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	Ethan Shotton (b) (4)	26 Feb 2021 18:53:02

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'mRNA-1273'	System	26 Feb 2021 20:31:46
DataPoint set to visible.	System	10 Feb 2021 21:20:36



US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

**US3342354**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:09:30**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered '12:57'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

**US3342354**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:09:30**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered '26 Feb 2021 12:57'	System	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'ONCE'	System	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 20:31:46

US3342354

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	26 Feb 2021 18:53:07

**US3342354**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'I'	System	26 Feb 2021 18:53:07



**US3342354**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:09:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:49:59

US3342354

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:36:59
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'can confirm safety call out of window, protocol deviation logged.' (Site from System).	Olivia Hapanowicz (b) (4) (b) (4)	12 Mar 2021 17:19:31
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Mar 2021 19:49:59
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 19:49:59

US3342354

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	09 Mar 2021 22:23:19
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	09 Mar 2021 19:49:59

US3342354

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:23:19
User entered '3 ATTEMPTED PHONE CALLS.'	(b) (4), (b) (6)	09 Mar 2021 19:49:59

**US3342354**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:50:28

**US3342354**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:42:57
User entered 'I'	System	09 Mar 2021 19:50:28

**US3342354**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:53:51
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '06 Apr 2021'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:53:51
	(b) (4)	



US3342354

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered 'Clinic (Clinic)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:53:51
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:30**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 16:53:51

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '06 Apr 2021'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '11:43'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 11:43'	System	06 Apr 2021 16:54:30

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '98.5' F	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered 'Oral (Oral)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	



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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '104'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 16:54:30

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '12'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 16:54:30

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '144'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	

**US3342354**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 16:54:30

US3342354

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered '91'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:54:30
	(b) (4)	



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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:09:30**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 16:54:30

**US3342354**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:09:30**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:55:43
	(b) (4)	

US3342354

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	06 Apr 2021 16:55:43
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:31:45

US3342354

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:31:45

**US3342354**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:30**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:57:32
User entered '11:59'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:31:45

**US3342354**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 11:59'	System	08 Apr 2021 16:31:45

US3342354

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:09:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:48
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:04:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:45:27
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	14 Dec 2020 20:28:29



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:08:41
User entered	System	15 Dec 2020 15:08:34
'USA-US203-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 15:08:34

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 20:10:20
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 23:42:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 23:42:13
Data point term sent to Coder	System	20 Jan 2021 23:41:03
Coding entries removed.	Stefanie Mott (b) (4)	20 Jan 2021 23:40:54
User entered 'Diabetic Ketoacidosis' reason for change: New Information	Stefanie Mott (b) (4)	20 Jan 2021 23:40:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:34:42
Data point term sent to Coder	System	14 Dec 2020 20:33:51
User entered 'hyperglycemia'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '11 Dec 2020'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:33:19



**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '13 Dec 2020'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Grade 4 (Grade 4)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19



US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '11 Dec 2020'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '13 Dec 2020'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	14 Dec 2020 20:33:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Applicable (NOT APPLICABLE)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 13:37:30
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). ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 13:37:28
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). ' answered with 'medications and procedures added ' (Site from Safety).	Stefanie Mott (b) (4)	21 Jan 2021 18:02:38
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with '12/12/20 (on admission) glucose 461 (70-105 mg/dL) pH- 7.24 (7.32-7.45) WBC-17.0 (4.8-10.8) Urine glucose >or=500 mg/dL lactic acid- 2.2 (<2.0 mmol/L) Abd/Pelvis CT with IV contrast 12/12/20- no acute CT abnormality of abdomen or pelvis identified. multiple segments of stool-filled descending and rectosigmoid colon. Chest XRAY- no sign of active disease' (Site from Safety).	Stefanie Mott (b) (4)	21 Jan 2021 17:32:10
User closed query 'PV Query: Please provide the last dates that diabetes medications (sitagliptin, insulin, and metformin) were taken prior to the event.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:46:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:46:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'not done' (Site from Safety).	Stefanie Mott (b) (4)	21 Jan 2021 14:04:36
Query 'PV Query: Please provide the last dates that diabetes medications (sitagliptin, insulin, and metformin) were taken prior to the event.' answered with 'edc and source updated with end date for insulin and sitagliptin. pt was still taking metformin' (Site from Safety).	Stefanie Mott (b) (4)	21 Jan 2021 14:01:13
User opened query 'PV Query: Please provide the last dates that diabetes medications (sitagliptin, insulin, and metformin) were taken prior to the event.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 11:36:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 11:36:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 11:35:23
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). ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 11:34:57

US3342354

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT'S SYMPTOMS BEGAN THE EVENING OF 11DEC2020. PT REPORTS SHE WAS ADMITTeD TO THE HOPSITAL ON THE NIGHT OF 11DEC2020 DUE TO VOMITING AND UNCONTROLLED BLOOD SUGAR IN THE 400'S. PATIENT STATES THAT SHE STAYED IN THE ICU FOR 1 DAY ON AN INSULIN DRIP AND THEN WAS DISCHARGED ON 13DEC2020 ONCE BLOOD SUGAR WAS CONTROLLED AND STABLE. PATIENT STATES THAT SHE HAD RAN OUT OF DM TYPE II MEDICATIONS CAUSING THIS EVENT.' reason for change: Data Entry Error	Stefanie Mott (b) (4)	14 Dec 2020 20:33:52
User entered 'Patient's symptoms began the evening of 11Dec2020. pt reports she was admittd to the hopsital on the night of 11Dec2020 due to vomiting and uncontrolled blood sugar in the 400's. Patient states that she stayed in the ICU for 1 day on an insulin drip and then was discharged on 13Dec2020 once blood sugar was controlled and stable. Patient states that she had ran out of DM type II medications causing this event.'	Stefanie Mott (b) (4)	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:33:19

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:33:19

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:57:12
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:11:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:11:52
Data point term sent to Coder	System	16 Mar 2021 15:11:06
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' answered with 'AE split, EDC updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:10:31
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:10:13
User entered 'EXACERBATION OF DEPRESSION' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:10:13
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update AE term to indicate a single underlying medical condition/diagnosis or split events and record them as separate AEs. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 04:24:35
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Anxiety depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:48:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:48:04
Data point term sent to Coder	System	21 Jan 2021 14:00:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'exacerbation of depression and anxiety'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '23 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:09:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 13:59:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49



US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:09:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 14:00:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 14:00:09
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 14:00:09
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 13:59:49
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49



US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 13:59:49



US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Applicable (NOT APPLICABLE)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:59:49

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 14:00:09



**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 13:59:49

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:12:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:12:51
Data point term sent to Coder	System	16 Mar 2021 15:12:09
User entered 'exacerbation of anxiety'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '23 Dec 2020'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 15:11:50



**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50



US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50



US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Not Applicable (NOT APPLICABLE)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'I'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50



US3342354

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:30:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:10:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 15:11:50

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 15:11:50

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 14:23:53
User entered		
'USA-US203-2021-mRNA-1273-P301000016'	System	30 Apr 2021 14:23:49
User entered 'New'	(b) (4), (b) (6)	30 Apr 2021 14:23:49

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Septicemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Apr 2021 20:59:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:59:21
Data point term sent to Coder	System	29 Apr 2021 20:57:55
User entered 'Septicemia'	(b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30



US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	29 Apr 2021 20:57:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Apr 2021 20:57:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:57:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Apr 2021 20:57:30
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Apr 2021 20:57:30
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:57:49
User entered '18 Apr 2021 UN:UN' (non-conformant).	System	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30



US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '24 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '3'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30



US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30



**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

US3342354

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Pt. went to North East Methodist Hospital on 18 Apr 2021 due to sx of UTI and high blood sugar. While in hospital pt. had difficulty breathing. After CT scan physician "found fluid in [her] chest". Pt. admitted to "ICU for heart pts" where they stayed for 3 days. Pt. prescribed furovsemide 20 mg BID, Carvedilol 3.125 mg BID and Lisinopril 5 mg QD. Pt. discontinued Pravastatin all on 20Apr2021. Pt. discharged from hospital on 24Apr2021.'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:57:30

**US3342354**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:57:30

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:09:30

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:48
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:04:29
User closed query 'Per ETRTR: According to SAE "Hyperglycemia" CRF, medication was provided. Please add Medication dosing details in this folder for SAE "Hyperglycemia", thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 20:04:25
Query 'Per ETRTR: According to SAE "Hyperglycemia" CRF, medication was provided. Please add Medication dosing details in this folder for SAE "Hyperglycemia", thanks.' answered with 'CONMEDS FOR DIABETIC HYPERKERTOSIS ARE ENTERED' (Site from CRA).	Eileen Euperio (b) (4)	22 Jan 2021 21:32:22
User opened query 'Per ETRTR: According to SAE "Hyperglycemia" CRF, medication was provided. Please add Medication dosing details in this folder for SAE "Hyperglycemia", thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:47:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:25:15



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:27:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:27:19
Data point term sent to Coder	System	13 Oct 2020 16:26:23
User entered 'Pravastatin'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '20'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:26:23



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:56
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 20:58:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:58:56
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:56
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 20:58:56
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:58:56
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:26:23

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:26:23



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:26:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:26:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:46:16
Data point term sent to Coder User entered 'Amlodipine'	System (b) (4), (b) (6)	13 Oct 2020 16:44:57 13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '10'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:00



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:00



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:44:00

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:44:00

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 16:44:00

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:46:16
Data point term sent to Coder	System	13 Oct 2020 16:45:00
User entered 'Metformin'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Type II Diabetes'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '500'	(b) (4), (b) (6)	13 Oct 2020 16:44:58



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 16:44:58



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:44:58

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 16:44:58

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:44:58

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:44:58

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 16:44:58

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:30:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:30:24
Data point term sent to Coder	System	13 Oct 2020 17:29:55
User entered 'Sitagliptin'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Type II Diabetes'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '50'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2013'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:49:46
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '11 Dec 2020' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:49:46
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:29:18

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User entered '1'	System	13 Oct 2020 17:29:18

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User entered '1'	System	13 Oct 2020 17:29:18

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:50
User entered '804 (804)'	System	13 Oct 2020 17:29:18



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:15:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:15:30
Data point term sent to Coder	System	13 Oct 2020 17:30:56
User entered 'Fluoxetine'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Anxiety & Depression'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '20'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2018'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:30:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 17:30:26



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 17:30:26

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 17:30:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:15:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:55:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:55:28
Data point term sent to Coder	System	13 Oct 2020 17:31:57
User entered 'Bupropion'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Anxiety & Depression'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '100'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2018'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 17:31:27

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 17:31:27

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: HUMULIN 70/30 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:33:26
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 Oct 2020 20:33:26
Data point term sent to Coder	System	13 Oct 2020 17:33:01
User entered '70/30 Insulin'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Type II Diabetes'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '42'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'units'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'twice daily (BID)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 2013'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:50:07
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '11 Dec 2020' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:50:07
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:32:56

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User entered '2'	System	13 Oct 2020 17:32:56

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User entered '1'	System	13 Oct 2020 17:32:56

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:22
User entered '804 (804)'	System	13 Oct 2020 17:32:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:35:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:35:28
Data point term sent to Coder	System	13 Oct 2020 17:34:02
User entered 'Ibuprofen'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Headaches'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '400'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'as needed (PRN)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UN UNK 1985'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	13 Oct 2020 17:33:38

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:33:38

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:33:38

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:33:38



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
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 Nov 2020 07:53:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:53:19
Data point term sent to Coder	System	19 Nov 2020 21:21:56
User entered 'Ibuprofen'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE POST VACCINE #2 AR is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE POST VACCINE #2 AR did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 14:39:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE POST VACCINE #2 AR is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE POST VACCINE #2 AR did not meet the AE reporting criteria. ' answered with 'Can confirm did not meet AE reporting criteria' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	15 Jan 2021 15:14:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

[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 timeframe. If the HEADACHE POST VACCINE #2 AR is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE POST VACCINE #2 AR did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:01:41
User entered 'Headache post vaccine #2 AR'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '400'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '14 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '14 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 21:21:26



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User entered empty.	System	19 Nov 2020 21:21:26

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User entered empty.	System	19 Nov 2020 21:21:26

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:29:52
User entered empty.	System	19 Nov 2020 21:21:26

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: OXCARBAZEPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:51:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:51:01
Data point term sent to Coder	System	21 Jan 2021 13:57:02
Data point term sent to Coder	System	21 Jan 2021 13:55:01
User entered 'oxcarbazepine'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'ANXIETY AND DEPRESSION exacerbation' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:56:11
User entered 'anxiety and depression'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '300'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 13:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 13:55:56
User entered 'once daily (QD)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 13:55:56
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 13:54:12
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '5 Jan 2021'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:54:12

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 13:55:56
User entered empty.	System	21 Jan 2021 13:54:12

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 13:55:56
User entered empty.	System	21 Jan 2021 13:54:12

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 13:55:56
User entered empty.	System	21 Jan 2021 13:54:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 13:59:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 13:59:00
Data point term sent to Coder	System	21 Jan 2021 13:58:02
User entered 'sitagliptin'	Stefanie Mott (b) (4) (b) (4) (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'type II diabetes mellitus'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '50'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '13 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:57:12

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 13:57:12

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 13:57:12

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 13:57:12

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:52:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 14:52:01
Data point term sent to Coder	System	21 Jan 2021 13:59:03
User entered 'novolog 70/30 insulin'	Stefanie Mott (b) (4) (b) (4)	21 Jan 2021 13:58:10



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'type II diabetes mellitus'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '42'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:30**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'units'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'other (OTHER)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 15:39:11
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'QAM' reason for change: Data Entry Error	Stefanie Mott (b) (4)	21 Jan 2021 15:39:11
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 13:58:10



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '13 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 13:58:10

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:39:11
User entered '1'	System	21 Jan 2021 13:58:10

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:39:11
User entered '1'	System	21 Jan 2021 13:58:10



**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:39:11
User entered '804 (804)'	System	21 Jan 2021 13:58:10

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:40:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:40:02
Data point term sent to Coder	System	21 Jan 2021 15:39:11
User entered 'novolog 70/30 insulin'	Stefanie Mott (b) (4)  (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'type II diabetes mellitus'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '32'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:09:30**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'units'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Qpm'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '13 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 15:38:56



**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:38:56

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:38:56

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 15:38:56

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:51:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:51:14
Data point term sent to Coder	System	21 Jan 2021 18:00:20
User entered 'regular insulin'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Diabetic ketoacidosis AE'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '8'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'units'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 17:59:59

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User entered empty.	System	21 Jan 2021 17:59:59

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User entered empty.	System	21 Jan 2021 17:59:59

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:32
User entered empty.	System	21 Jan 2021 17:59:59

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:19:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:19:05
Data point term sent to Coder	System	21 Jan 2021 18:01:21
User entered 'ceftriaxone sodium'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:09:30**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'diabetic ketoacidosis AE'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'l'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'g (g)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:00:39

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User entered empty.	System	21 Jan 2021 18:00:39

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User entered empty.	System	21 Jan 2021 18:00:39

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:42
User entered empty.	System	21 Jan 2021 18:00:39

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:56:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:56:11
Data point term sent to Coder	System	21 Jan 2021 18:02:21
User entered 'iopamidol'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'diabetic ketoacidosis AE'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '75'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mL (mL)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:01:25

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User entered empty.	System	21 Jan 2021 18:01:25

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User entered empty.	System	21 Jan 2021 18:01:25



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:40
User entered empty.	System	21 Jan 2021 18:01:25

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:44:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:44:14
Data point term sent to Coder	System	21 Jan 2021 18:02:21
User entered 'ondasteron'	Stefanie Mott (b) (4) (b) (4) (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'diabetic ketoacidosis ae'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '4'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mg (mg)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:09



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User entered empty.	System	21 Jan 2021 18:02:09

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User entered empty.	System	21 Jan 2021 18:02:09

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:34:17
User entered empty.	System	21 Jan 2021 18:02:09

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:30:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:30:17
Data point term sent to Coder	System	21 Jan 2021 18:15:38
User entered 'humulin R insulin drip'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'diabetic ketoacidosis AE'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'UNK'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'units'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:03

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User entered empty.	System	21 Jan 2021 18:15:03

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User entered empty.	System	21 Jan 2021 18:15:03

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:17:25
User entered empty.	System	21 Jan 2021 18:15:03

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:17:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 06:01:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 06:01:25
Data point term sent to Coder	System	21 Jan 2021 18:16:39
User entered 'Normal saline'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'diabetic ketoacidosis AE'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '150'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'mL/hr'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'Intravenous (INTRAVENOUS)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57



**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '0'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:17:38
User entered 'No (N)'	Stefanie Mott (b) (4)	21 Jan 2021 18:15:57

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User entered empty.	System	21 Jan 2021 18:15:57

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User entered empty.	System	21 Jan 2021 18:15:57

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:39
User entered empty.	System	21 Jan 2021 18:15:57

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Apr 2021 04:23:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:23:18
Data point term sent to Coder	System	29 Apr 2021 21:02:17
User entered 'Furosemide'	(b) (4), (b) (6) (b) (4)	29 Apr 2021 21:02:08



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Septicemia SAE'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '20'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:02:08

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 21:02:08

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:02:08



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:02:08

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Apr 2021 23:02:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:02:16
Data point term sent to Coder	System	29 Apr 2021 21:06:22
Data point term sent to Coder	System	29 Apr 2021 21:04:20
User entered 'Carvedilol'	(b) (4), (b) (6) (b) (4)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'SEPTICEMIA SAE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:05:39
User entered 'Septicemia'	(b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '3.125'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:03:28



**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:03:28

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:03:28

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Apr 2021 05:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:07:29
Data point term sent to Coder	System	29 Apr 2021 21:06:22
User entered 'Lisinopril'	(b) (4), (b) (6) (b) (4)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Septicemia SAE'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '5'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23



US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23



US3342354

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:05:23

**US3342354**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 21:05:23

US3342354

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 21:05:23

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:09:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:48
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:38:27
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	21 Jan 2021 18:02:46

US3342354

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:09:30**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:03:05

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered 'chest xray'	Stefanie Mott (b) (4)	21 Jan 2021 18:03:05



US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered 'Adverse Event (AE)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	21 Jan 2021 18:03:05

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:30

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:03:05

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:35
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered '12 Dec 2020'	Stefanie Mott (b) (4)	21 Jan 2021 18:03:28

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:35
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered 'abdominal/pelvis CT with contrast'	Stefanie Mott (b) (4)	21 Jan 2021 18:03:28

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:35
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered 'Adverse Event (AE)'	Stefanie Mott (b) (4)	21 Jan 2021 18:03:28

US3342354

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:35
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:41:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:39:36
User entered empty.	Stefanie Mott (b) (4)	21 Jan 2021 18:03:28

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'USA-US203-2020-MRNA-1273-P301000011'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34



**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Paul'	(b) (4) System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Pickrell'	(b) (4) System	30 Apr 2021 14:23:49



**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:37:24
User entered 'US'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 13:37:51
User entered '2'	System	21 Jan 2021 16:37:33
User entered '1'	System	15 Dec 2020 15:10:13

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'USA-US203-2020-MRNA-1273-P301000011'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34



**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Paul'	(b) (4) System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Pickrell'	(b) (4) System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:37:24
User entered 'US'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 13:37:51
User entered '2'	System	21 Jan 2021 16:37:33
User entered '1'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
User entered '15/Dec/2020 10:10'	System	15 Dec 2020 15:10:13

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:30

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:37:24
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 15:10:13



US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'USA-US203-2020-MRNA-1273-P301000011'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34



US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Paul'	(b) (4) System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Pickrell'	(b) (4) System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:37:24
User entered 'US'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 13:37:51
User entered '2'	System	21 Jan 2021 16:37:33
User entered '1'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:09:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
User entered '21/Jan/2021 16:37'	System	21 Jan 2021 16:37:33

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:30

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 13:37:41
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 16:37:33

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'USA-US203-2020-MRNA-1273-P301000011'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34



**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'Yes (Y)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 15:09:54
User entered 'No (N)'	System	15 Dec 2020 15:08:34

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Paul'	(b) (4) System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'Pickrell'	(b) (4) System	30 Apr 2021 14:23:49



**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:37:24
User entered 'US'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Jan 2021 13:37:51
User entered '2'	System	21 Jan 2021 16:37:33
User entered '1'	System	15 Dec 2020 15:10:13

**US3342354**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:09:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:23:43
User entered '22/Jan/2021 08:37'	System	22 Jan 2021 13:37:51

US3342354

Folder: SAE USA-US203-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:30

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 22:13:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 20:23:43
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 13:37:51

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'USA-US203-2021-MRNA-1273-P301000016'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49



**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Paul'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Pickrell'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'US'	(b) (4) System	30 Apr 2021 14:24:13

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 14:24:13



**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'USA-US203-2021-MRNA-1273-P301000016'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Yes (Y)'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'No (N)'	System	30 Apr 2021 14:23:49



**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Paul'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:04
User entered 'Pickrell'	System	30 Apr 2021 14:23:49

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'US'	(b) (4) System	30 Apr 2021 14:24:13

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 14:24:13

**US3342354**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000016**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:09:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered '30/Apr/2021 09:24'	(b) (4) System	30 Apr 2021 14:24:13

US3342354

Folder: SAE USA-US203-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:30

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	30 Apr 2021 22:18:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:24:13