

US3142139 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:26:33

All time stamps listed in this document are displayed in GMT

US3142139

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

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[Participant ID](#)

US3142139

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

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US3142139

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Date of Birth (MMM yyyy)	(b) (6)1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 20:16:55

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 20:16:55

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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) 18 Apr 2021 20:16:56

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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) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

Condition	FARSIGHTED
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 20:16:55

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

Condition	PARTIAL HEARING LOSS, BILATERAL
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

Condition	KIDNEY STONES, UNSPECIFIED LOCATION
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 20:16:55

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Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 20:16:55

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Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 20:16:55

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 20:16:55

Generated On: 09 Jun 2021 15:26:33

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	6 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:55 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:55
Height ( <i>xxx.x</i> )	63 in
Weight ( <i>xxx.x</i> )	155 lb
BMI ( <i>xxx.x</i> )	27.51443 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:56

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Apr 2021 20:16:54

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Date of assessment (dd MMM yyyy) 6 AUG 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 2002

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:56

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 185076

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) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

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) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

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)	6 AUG 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 14:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 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) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

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)	6 AUG 2020
Time of assessment (00:00-23:59)	16:02 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 16:02
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 15:42

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) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 AUG 2020
Collection time (00:00-23:59)	15:05 (24 HR)
Collection date and time (derived)	6 AUG 2020 15:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:05	6 AUG 2020 15:05
Nasopharyngeal Swab 2	Yes	15:05	6 AUG 2020 15:05



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:56

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 16:16

PC Open Date & Time

06 AUG 2020 16:02

PC Close Date & Time

06 AUG 2020 18:32

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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

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

06 AUG 2020 19:27

PC Close Date & Time

07 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**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

98.4 °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

07 AUG 2020 18:24

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**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

98.9 °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

08 AUG 2020 22:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**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

99.3 °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

09 AUG 2020 20:08

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**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

98.7 °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

10 AUG 2020 21:14

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**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

98.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 AUG 2020 21:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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

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

13 AUG 2020 00:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**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

06 AUG 2020 16:16

PC Open Date & Time

06 AUG 2020 16:02

PC Close Date & Time

06 AUG 2020 18:32

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

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.**

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

PC Open Date & Time

06 AUG 2020 19:27

PC Close Date & Time

07 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

25

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

07 AUG 2020 18:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**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

08 AUG 2020 22:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**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

09 AUG 2020 20:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**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

10 AUG 2020 21:14

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**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

11 AUG 2020 21:16

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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

13 AUG 2020 00:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:17
PC Open Date & Time	06 AUG 2020 16:02
PC Close Date & Time	06 AUG 2020 18:32

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 19:27

PC Close Date & Time

07 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**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

53 of 2273

EAB) (1725)

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:26
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2273

EAB) (1725)



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:15
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:09
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

59 of 2273

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 21:15
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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 ☒

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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 ☒



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 00:21
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3142139

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:26:33

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 14:08
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3142139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3142139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:10
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

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)	3 SEP 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:39
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3142139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 15:09 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 15:09

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

US3142139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	14:37 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:37

US3142139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:33	3 SEP 2020 14:33
Nasopharyngeal Swab 2	Yes	14:33	3 SEP 2020 14:33

US3142139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:57

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**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

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

03 SEP 2020 15:29

PC Close Date & Time

03 SEP 2020 17:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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

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

03 SEP 2020 18:54

PC Close Date & Time

04 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 01:24

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:26

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**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

98.2 °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

06 SEP 2020 21:40

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 00:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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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

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

09 SEP 2020 06:05

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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

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

09 SEP 2020 23:32

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

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

PC Open Date & Time

03 SEP 2020 15:29

PC Close Date & Time

03 SEP 2020 17:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

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.**

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

PC Open Date & Time

03 SEP 2020 18:54

PC Close Date & Time

04 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**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

05 SEP 2020 01:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**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

05 SEP 2020 19:26

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**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

06 SEP 2020 21:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**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

08 SEP 2020 00:32

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**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

09 SEP 2020 06:05

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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

09 SEP 2020 23:33

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 15:29

PC Close Date & Time

03 SEP 2020 17:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**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 ☐

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 18:54

PC Close Date & Time

04 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**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 ☒

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 01:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:25
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**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 ☒

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:41
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 00:32
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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 ☒

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 06:07
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**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 ☒

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 23:33
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59



US3142139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3142139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 13:31
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3142139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

8 OCT 2020

---

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

---

US3142139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	13:38 (24 HR)
Collection date and time (derived)	8 OCT 2020 13:38

US3142139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 09:41:44

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59



US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 22:42:27

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 20:19:38

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2020 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 19:24:59

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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

21 DEC 2020 05:58:59

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 18:28:26

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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

26 JAN 2021 00:47:05

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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

02 FEB 2021 02:05:25

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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

08 FEB 2021 23:40:29

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 10:43:49
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 23:58:40
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59



US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 12:56:54

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 21:04:54

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 08:45:54

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 12:44:22
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 08:26:15

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 07:07:05

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59



US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 APR 2021 07:12:35
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

<b>TIMEPOINT</b>	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 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	24 APR 2021 18:10:47
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 02:50:04

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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="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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	02 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59
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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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="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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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 <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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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="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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐ Yes ☐

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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°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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

24 AUG 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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"/>

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

**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 ☐

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

US3142139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2022 23:59

US3142139

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:26:33

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
Yes	No	27 FEB 2021 12:57:58

US3142139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

PT TAKING HYDROCODONE  
PRO POST SURGERY, PT TO  
REPORT START DATE,  
SURGERY DETAILS AND  
DOSAGE ONCE SHE IS AT HOME  
AN CAN REVIEW.

US3142139

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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*

US3142139

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3142139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:16:59

Generated On: 09 Jun 2021 15:26:33

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3142139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

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.*

US3142139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	15:03 (24 HR)
Collection date and time (derived)	4 MAR 2021 15:03

US3142139

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:58

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3142139**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

*If Contact Not Made, please provide Comments*



**US3142139**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3142139**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:26:33**

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"/>

**US3142139**

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

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

**Generated On: 09 Jun 2021 15:26:33**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3142139

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3142139

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Date of updated informed consent ( <i>dd MMM yyyy</i> )	28 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> )	28 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

US3142139

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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

US3142139

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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)	14:02 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:02
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3142139

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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 type="radio"/> No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	



US3142139

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3142139

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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) 15:38 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 15:38

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

US3142139

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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)	13:57 (24 HR)
Collection date and time (derived)	28 JAN 2021 13:57

US3142139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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)	13:58
Collection Date and Time (derived)	28 JAN 2021 13:58

US3142139

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

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

US3142139

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3142139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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)	04 MAR 2021
Time of assessment (00:00-23:59)	14:44 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 14:44
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3142139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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)	04 MAR 2021
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 15:50
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3142139

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3142139

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

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) 04 MAR 2021

What was the treatment time? (00:00-23:59) 15:20 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 15:20

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

US3142139

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:15

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142139

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:16:54

Generated On: 09 Jun 2021 15:26:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3142139**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

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 \_\_\_\_\_



US3142139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

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)	

US3142139

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

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.*

**US3142139**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3142139

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

AEID	USA-US064-2021-MRNA-1273-P30 1000010
Adverse event	HOSPITALIZATION DUE TO A KIDNEY STONE
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)	2 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 APR 2021
Hospital Discharge Date (dd MMM yyyy)	4 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HOSPITALIZED OVERNIGHT DUE TO KIDNEY STONE
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3142139

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:33

AEID	
Adverse event	RIGHT BROKEN WRIST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 SEP 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)	10 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 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	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:33

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



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 May 2021 15:03:33

Generated On: 09 Jun 2021 15:26:33

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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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US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 ☐  
Intraocular ☐

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EAB) (1725)

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US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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 2008	
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"/>

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication PRISTIQ

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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 2012	
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) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication AMBIEN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication LITHIUM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 150

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) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication SYMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPER-CHOLESTEROL

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) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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 2012	
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) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication HYDROCODONE  
ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication DENTAL PAIN AFTER DENTAL  
SURGERY

Dose per administration 5/325

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

If dose unit is Other, specify MG/MG

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 AUG 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 (7)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AFTER DENTAL SURGERY

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication HYDROCODONE

Prophylaxis Yes ☐  
No ☒

Indication PAIN AFTER DENTAL SURGERY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 AUG 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 (9)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication OXYCOTIN

Prophylaxis Yes ☒  
No ☐

Indication PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (11)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication OSEOBIFLEX

Prophylaxis Yes ☒  
No ☐

Indication BONE HEALTH

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (12)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN

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 (12)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 MAR 2021	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 20:16:14

Generated On: 09 Jun 2021 15:26:33

	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)		08 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 MAR 2021
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"/>

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 02:41:34

Generated On: 09 Jun 2021 15:26:33

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 02:41:34

Generated On: 09 Jun 2021 15:26:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 SEP 2020	FRACTURED RIGHT WRIST SURGICAL REPAIR	Adverse Event	
05 APR 2021	RIGHT KIDNEY STONE REMOVAL	Adverse Event	
05 APR 2021	RIGHT KIDNEY STENT PLACEMENT RELATED TO KIDNEY STONE	Adverse Event	
15 APR 2021	REMOVAL OF RIGHT KIDNEY STONE RELATED TO KIDNEY STONE	Adverse Event	

US3142139

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:26:33

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

US3142139

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:26:33

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 ☐

US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:33

SAEID	USA-US064-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3



US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:26:33

SAEID	USA-US064-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 17:50
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

US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:26:33

SAEID	USA-US064-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 17:51
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

US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:26:33

SAEID	USA-US064-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 11:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142139 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

**US3142139**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:26:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:06:13
User entered 'US3142139'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:44:31

**US3142139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:30
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:44:12

US3142139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:26:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:30
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:44:32

**US3142139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:29:30
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	06 Aug 2020 21:44:12



**US3142139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'SCRN'	System	06 Aug 2020 21:44:12

US3142139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:26:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '(b) (6)1950'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:44:33

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '69'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'YEARS'	System	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '69'	System	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered 'Female (F)'	Meghan York (b) (4)	07 Aug 2020 14:10:27

US3142139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:26:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

**White**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered 'l'	Meghan York (b) (4)	07 Aug 2020 14:10:27



**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27

**US3142139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:26:33**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:29:50
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:10:27



US3142139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:26:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered '6 Aug 2020'	Meghan York (b) (4)	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Aug 2020'	System	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	06 Aug 2020 21:44:30

US3142139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:26:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:06:48
DataPoint Un-verified.	Meghan York (b) (4)	09 Dec 2020 23:18:52
User entered 'Amendment 2 (2)' reason for change:	Meghan York (b) (4)	09 Dec 2020 23:18:52
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered 'Amendment 1 (1)'	Meghan York (b) (4)	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:44:30

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered 'No (N)'	Meghan York (b) (4)	06 Aug 2020 21:44:30



**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:30:44
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:44:32

**US3142139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:26:33**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'I'	System	06 Aug 2020 21:44:35

**US3142139**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:26:33**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:31:08
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:44:35

**US3142139**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 15:26:33**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:07:44
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:10:35

US3142139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:12:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:12:12
Data point term sent to Coder	System	07 Aug 2020 14:11:27
User entered 'farsighted'	Meghan York (b) (4)	07 Aug 2020 14:11:19
	(b) (4)	

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 2010'	Meghan York (b) (4)	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:11:19



**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2010'	System	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2010'	System	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:11:19

**US3142139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:11:19

US3142139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).		15 Oct 2020 13:21:12
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:24:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:24:15
Query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'term updated' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:23:44
Data point term sent to Coder	System	13 Oct 2020 20:23:36
Coding entries removed.	Jami Wagner (b) (4)	13 Oct 2020 20:23:33
User entered 'CATARACTS, bilateral' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:23:33
User opened query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:23:26
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:13:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:13:17
Data point term sent to Coder	System	07 Aug 2020 14:12:28
User entered 'cataracts'	Meghan York (b) (4)	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN Jan 2020'	Meghan York (b) (4)	07 Aug 2020 14:11:58



**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:11:58

US3142139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:26:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).		15 Oct 2020 13:21:37
Query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' answered with 'cataract surgery added to MH' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:27:36
User opened query 'Per DM CLR: Please note that stop date is unexpected for chronic condition, if patient underwent the surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:29:21
User entered 'UN Jan 2020'	Meghan York (b) (4)	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2020'	System	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2020'	System	07 Aug 2020 14:11:58

**US3142139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	07 Aug 2020 14:11:58



US3142139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Partial hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 15:17:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 15:17:56
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).		15 Oct 2020 13:21:49
Data point term sent to Coder	System	13 Oct 2020 20:28:43
Query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'term updated' (Site from DM).	Jami Wagner (b) (4)	13 Oct 2020 20:28:25
Coding entries removed.	Jami Wagner (b) (4)	13 Oct 2020 20:28:18
User entered 'PARTIAL HEARING LOSS, bilateral' reason for change: Data Entry Error	Jami Wagner (b) (4)	13 Oct 2020 20:28:18
User opened query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:29:41
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Partial hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:13:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:13:17
Data point term sent to Coder	System	07 Aug 2020 14:12:28
User entered 'partial hearing loss'	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 1965'	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1965'	System	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1965'	System	07 Aug 2020 14:12:27



**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:12:27

**US3142139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:12:27

US3142139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:14:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:14:08
Data point term sent to Coder	System	07 Aug 2020 14:13:29
User entered 'tonsillitis'	Meghan York (b) (4)	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 1960'	Meghan York (b) (4)	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 1960'	Meghan York (b) (4)	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:13:07



**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1960'	System	07 Aug 2020 14:13:07

**US3142139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1960'	System	07 Aug 2020 14:13:07

US3142139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please specify the location of Kidney Stones (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).		15 Oct 2020 13:21:58
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:09:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 23:09:26
Data point term sent to Coder	System	13 Oct 2020 20:29:44
Query 'Per DM CLR: Please specify the location of Kidney Stones (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'term updated' (Site from DM).	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:29:28
Coding entries removed.	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:29:12
User entered 'KIDNEY STONES, unspecified location' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:29:12
User opened query 'Per DM CLR: Please specify the location of Kidney Stones (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:30:19
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:15:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:15:17
Data point term sent to Coder	System	07 Aug 2020 14:14:29
User entered 'kidney stones'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN Mar 2020'	Meghan York (b) (4)	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:13:44



US3142139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:26:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF. ' (Site from DM).		15 Oct 2020 13:22:28
Query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF. ' answered with 'eCRF is correct. Subject reported the stop date for this condition' (Site from DM).	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:31:36
User opened query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:30:38
User entered 'UN Mar 2020'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Mar 2020'	System	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Mar 2020'	System	07 Aug 2020 14:13:44

**US3142139**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	07 Aug 2020 14:13:44

US3142139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:26:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
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)	07 Aug 2020 14:16:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:16:12
Data point term sent to Coder	System	07 Aug 2020 14:15:30
User entered 'hypercholesterolemia'	Meghan York (b) (4)	07 Aug 2020 14:14:48
	(b) (4)	

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 2012'	Meghan York (b) (4)	07 Aug 2020 14:14:48



**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2012'	System	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2012'	System	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:14:48

**US3142139**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:14:48



US3142139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:26:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:34:28
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).		15 Oct 2020 13:25:59
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'subject reported no medications taken for this condition' (Site from DM).	Jami Wagner (b) (4) (b) (4)	13 Oct 2020 20:34:12
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:31:04
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:16:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 14:16:13
Data point term sent to Coder	System	07 Aug 2020 14:15:31
User entered 'hypothyroidism'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 1980'	Meghan York (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1980'	System	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1980'	System	07 Aug 2020 14:15:21



**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:15:21

**US3142139**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:15:21

US3142139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:26:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:17:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:17:15
Data point term sent to Coder	System	07 Aug 2020 14:16:32
User entered 'post menopausal'	Meghan York (b) (4)	07 Aug 2020 14:15:55
	(b) (4)	

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 2002'	Meghan York (b) (4)	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:15:55



**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2002'	System	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2002'	System	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:15:55

**US3142139**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:15:55

US3142139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:26:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:17:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:17:14
Data point term sent to Coder	System	07 Aug 2020 14:16:32
User entered 'depression'	Meghan York (b) (4)	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 1965'	Meghan York (b) (4)	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:16:29



**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 1965'	System	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '1965'	System	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:16:29

**US3142139**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:16:29

US3142139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:26:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:19:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:19:10
Data point term sent to Coder	System	07 Aug 2020 14:17:34
User entered 'insomnia'	Meghan York (b) (4)	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'UN UNK 2014'	Meghan York (b) (4)	07 Aug 2020 14:16:48



**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2014'	System	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2014'	System	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:16:48

**US3142139**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered empty.	System	07 Aug 2020 14:16:48



US3142139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:26:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:28:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:28:34
Data point term sent to Coder	System	13 Oct 2020 20:27:41
User entered 'Cataract Surgery, bilateral'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'un Jan 2020'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'No (N)'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered 'un Jan 2020'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:34:28
User entered '0'	Jami Wagner (b) (4)	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2020'	System	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	13 Oct 2020 20:26:47



**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'Jan 2020'	System	13 Oct 2020 20:26:47

**US3142139**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '2020'	System	13 Oct 2020 20:26:47

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered '14:55'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered '6 Aug 2020 14:55'	System	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered '63' in	Meghan York (b) (4)	07 Aug 2020 14:18:16
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:44:35

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered '155' lb	Meghan York (b) (4)	07 Aug 2020 14:18:16
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:44:35



**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
Amendment Manager: User entered '27.51443'	System	16 Sep 2020 23:46:28
User entered '27.5'	System	07 Aug 2020 14:18:16
DataPoint set to visible.	System	06 Aug 2020 21:44:35

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'kg/m2'	System	07 Aug 2020 14:18:16
DataPoint set to visible.	System	06 Aug 2020 21:44:35

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).		30 Sep 2020 16:55:17
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4)	25 Sep 2020 18:49:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 19:09:03
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:52:56
User entered '97.7' F	Meghan York (b) (4)	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered 'Other (Other)'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered '66'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'bpm'	System	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered '20'	Meghan York (b) (4)	07 Aug 2020 14:18:16



US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'breaths/min'	System	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered '118'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'mmHg'	System	07 Aug 2020 14:18:16

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:09:03
User entered '77'	Meghan York (b) (4)	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User entered 'mmHg'	System	07 Aug 2020 14:18:16

**US3142139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41

US3142139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41

**US3142139**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:25
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:18:27



US3142139

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:35:28
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		13 Sep 2020 14:31:11
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 16:33:04
User entered '6 Aug 2020'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:18:27

US3142139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:18:58

**US3142139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:18:58

US3142139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:26:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Meghan York (b) (4)	07 Aug 2020 14:18:58

**US3142139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:33**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:18:58

**US3142139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:18:58

**US3142139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:33**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:18:58

US3142139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered 'UN UNK 2002'	Meghan York (b) (4)	07 Aug 2020 14:18:58



**US3142139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:26:33**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:35:36
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:18:58

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22



US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
User entered '0'	(b) (4) Meghan York (b) (4)	07 Aug 2020 14:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered '0'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:19:22



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered '0'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered '0'	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered 'I'	Meghan York (b) (4)	07 Aug 2020 14:19:22

**US3142139**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:26:33**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
User entered '0'	(b) (4) Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:26:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:36:19
User entered empty.	Meghan York (b) (4)	07 Aug 2020 14:19:22

US3142139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:26:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:00
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:19:38

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:00
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:19:38



**US3142139**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:00
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	07 Aug 2020 14:19:38

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'VISIT1'	System	07 Aug 2020 14:19:38

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:39:22

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:42:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:42:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:39:22
User entered '185076' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:39:22

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:39:22

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

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)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:20:16

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

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)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:20:16

US3142139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:26:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:20:16



**US3142139**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:33**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:20:16

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:33**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:09
User entered 'No (N)'	Meghan York (b) (4)	07 Aug 2020 14:20:16

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:26:33**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
DataPoint set to visible.	System	09 Dec 2020 23:18:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:13:38

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:26
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:55:25
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:49:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:08:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:52
User entered '63' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:08:37
User entered '155' lb	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:26
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:55:25
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:49:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:08:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:52
User entered '63' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:08:37
User entered '155' lb	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33



US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:55
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:59
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:58
User entered '14:55'	Meghan York (b) (4)	07 Aug 2020 14:22:33

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 14:55'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:01
User entered '97.7' F	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:05
User entered 'Other (Other)'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:03
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '66'	Meghan York (b) (4)	07 Aug 2020 14:22:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'bpm'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:07
User entered '20'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'breaths/min'	System	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:09
User entered '118'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:20
User entered '77'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:37:26
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:55:25
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:49:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:08:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:31:52
User entered '63' in	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33



US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:37:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:08:37
User entered '155' lb	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:38:50
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		18 Aug 2020 18:07:43
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 14:22:33
User entered '16:02'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:22:33

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 16:02'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '97.1' F	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered 'Other (Other)'	Meghan York (b) (4)	07 Aug 2020 14:22:33



**US3142139**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered 'temporal'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '55'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'bpm'	System	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '18'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'breaths/min'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '129'	Meghan York (b) (4)	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	07 Aug 2020 14:22:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:38:50
User entered '87'	Meghan York (b) (4)	07 Aug 2020 14:22:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	07 Aug 2020 14:22:33

US3142139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:39:37
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:49:31
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:22:45

US3142139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:39:37
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:49:31
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:22:45

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered 'Yes (Y)'	Meghan York (b) (4)	06 Aug 2020 21:45:08

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:45:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered empty.	Meghan York (b) (4)	06 Aug 2020 21:45:08

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 21:45:08

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered '6 Aug 2020'	Meghan York (b) (4)	06 Aug 2020 21:45:08



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered '15:42'	Meghan York (b) (4)	06 Aug 2020 21:45:08

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 15:42'	System	06 Aug 2020 21:45:08

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	06 Aug 2020 21:45:08

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:01
User entered 'ONCE'	System	06 Aug 2020 21:45:08

US3142139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:33
User entered 'Yes (Y)'	Meghan York (b) (4)	07 Aug 2020 14:23:05

US3142139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:33
User entered '6 Aug 2020'	Meghan York (b) (4)	07 Aug 2020 14:23:05

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:40:33
User entered '15:05'	Meghan York (b) (4)	07 Aug 2020 14:23:05



**US3142139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 15:05'	System	07 Aug 2020 14:23:05

US3142139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:26:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:27
User entered '6 Aug 2020'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

US3142139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:26:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

US3142139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:26:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:27
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:27
User entered '15:05'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 15:05'	System	07 Aug 2020 14:23:26

US3142139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:26:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

US3142139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:26:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:27
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26



**US3142139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:27
User entered '15:05'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:26

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '6 Aug 2020 15:05'	System	07 Aug 2020 14:23:26

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:09:36
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	07 Aug 2020 14:23:31

**US3142139**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	07 Aug 2020 14:23:31

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:15:46', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6e672b22-64df-47fa-b1a7-0f9302a2254b'	System	06 Aug 2020 22:15:26
User entered 'Yes (Y)'	System	06 Aug 2020 22:15:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:15:57', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6e672b22-64df-47fa-b1a7-0f9302a2254b' User entered '97.1'	System	06 Aug 2020 22:15:26
	System	06 Aug 2020 22:15:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:03', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6e672b22-64df-47fa-b1a7-0f9302a2254b'	System	06 Aug 2020 22:15:26
User entered 'No (N)'	System	06 Aug 2020 22:15:26



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:10', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6e672b22-64df-47fa-b1a7-0f9302a2254b'	System	06 Aug 2020 22:15:26
User entered '06 Aug 2020 16:16'	System	06 Aug 2020 22:15:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 16:02'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 18:32'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 19:27'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 2'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:24:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3676a2db-6d09-4fcd-a8ec-ee3c2de530c0'	System	08 Aug 2020 00:23:56
User entered 'Yes (Y)'	System	08 Aug 2020 00:23:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:24:20', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3676a2db-6d09-4fcd-a8ec-ee3c2de530c0'	System	08 Aug 2020 00:23:56
User entered '98.4'	System	08 Aug 2020 00:23:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:24:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3676a2db-6d09-4fcd-a8ec-ee3c2de530c0'	System	08 Aug 2020 00:23:56
User entered 'No (N)'	System	08 Aug 2020 00:23:56



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:24:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3676a2db-6d09-4fcd-a8ec-ee3c2de530c0'	System	08 Aug 2020 00:23:56
User entered '07 Aug 2020 18:24'	System	08 Aug 2020 00:23:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 3'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:13:55', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'd0727113-dc8e-464c-a8f3-199b0772db33'	System	09 Aug 2020 04:13:37
User entered 'Yes (Y)'	System	09 Aug 2020 04:13:37

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:10', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'd0727113-dc8e-464c-a8f3-199b0772db33'	System	09 Aug 2020 04:13:37
User entered '98.9'	System	09 Aug 2020 04:13:37

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:14', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'd0727113-dc8e-464c-a8f3-199b0772db33'	System	09 Aug 2020 04:13:37
User entered 'No (N)'	System	09 Aug 2020 04:13:37

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:21', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'd0727113-dc8e-464c-a8f3-199b0772db33'	System	09 Aug 2020 04:13:37
User entered '08 Aug 2020 22:14'	System	09 Aug 2020 04:13:37



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 4'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:07:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '69819564-1dbd-4191-81e5-a6ecb63baf49'	System	10 Aug 2020 02:07:44
User entered 'Yes (Y)'	System	10 Aug 2020 02:07:44

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:07:56', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '69819564-1dbd-4191-81e5-a6ecb63baf49'	System	10 Aug 2020 02:07:44
User entered '99.3'	System	10 Aug 2020 02:07:44

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:10', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '69819564-1dbd-4191-81e5-a6ecb63baf49'	System	10 Aug 2020 02:07:44
User entered 'No (N)'	System	10 Aug 2020 02:07:44

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '69819564-1dbd-4191-81e5-a6ecb63baf49'	System	10 Aug 2020 02:07:44
User entered '09 Aug 2020 20:08'	System	10 Aug 2020 02:07:44

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 5'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:13:41', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5a5996be-fd39-4730-b907-86ed6dc0a17c'	System	11 Aug 2020 03:13:16
User entered 'Yes (Y)'	System	11 Aug 2020 03:13:16

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:13:50', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5a5996be-fd39-4730-b907-86ed6dc0a17c'	System	11 Aug 2020 03:13:16
User entered '98.7'	System	11 Aug 2020 03:13:16

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:13:55', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5a5996be-fd39-4730-b907-86ed6dc0a17c'	System	11 Aug 2020 03:13:16
User entered 'No (N)'	System	11 Aug 2020 03:13:16

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:02', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5a5996be-fd39-4730-b907-86ed6dc0a17c'	System	11 Aug 2020 03:13:16
User entered '10 Aug 2020 21:14'	System	11 Aug 2020 03:13:16

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 6'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:08', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered 'Yes (Y)'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:16', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered '98.7'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered 'Yes (Y)'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
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).		19 Nov 2020 07:11:44
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. Medication is now listed under ConMed page. ' (Site from System).	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:02:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 03:14:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:35', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered '1'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:35', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered '0'	System	12 Aug 2020 03:14:56

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:43', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'df44295a-7a57-42dc-b00a-15db403a5879'	System	12 Aug 2020 03:14:56
User entered '11 Aug 2020 21:15'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 7'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:15:13', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3148f926-3531-4caa-b2d6-2716aec2461d'	System	13 Aug 2020 06:19:26
User entered 'Yes (Y)'	System	13 Aug 2020 06:19:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3148f926-3531-4caa-b2d6-2716aec2461d' User entered '98.3'	System	13 Aug 2020 06:19:26
	System	13 Aug 2020 06:19:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:06', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3148f926-3531-4caa-b2d6-2716aec2461d'	System	13 Aug 2020 06:19:26
User entered 'No (N)'	System	13 Aug 2020 06:19:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:12', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3148f926-3531-4caa-b2d6-2716aec2461d'	System	13 Aug 2020 06:19:26
User entered '13 Aug 2020 00:20'	System	13 Aug 2020 06:19:26

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:21', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a7f88bad-5497-4263-959b-142160e4f10e'	System	06 Aug 2020 22:16:00
User entered 'None (1)'	System	06 Aug 2020 22:16:00

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:27', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a7f88bad-5497-4263-959b-142160e4f10e'	System	06 Aug 2020 22:16:00
User entered 'No (N)'	System	06 Aug 2020 22:16:00

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:31', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a7f88bad-5497-4263-959b-142160e4f10e'	System	06 Aug 2020 22:16:00
User entered 'No (N)'	System	06 Aug 2020 22:16:00

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:36', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a7f88bad-5497-4263-959b-142160e4f10e'	System	06 Aug 2020 22:16:00
User entered 'None (1)'	System	06 Aug 2020 22:16:00

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:45', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a7f88bad-5497-4263-959b-142160e4f10e'	System	06 Aug 2020 22:16:00
User entered '06 Aug 2020 16:16'	System	06 Aug 2020 22:16:00

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 16:02'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 18:32'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 19:27'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 2'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:26:33', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f'	System	08 Aug 2020 00:39:21
User entered 'None (1)'	System	08 Aug 2020 00:39:21

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:27:03', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f'	System	08 Aug 2020 00:39:21
User entered 'No (N)'	System	08 Aug 2020 00:39:21

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:27:32', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f'	System	08 Aug 2020 00:39:21
User entered 'Yes (Y)'	System	08 Aug 2020 00:39:21

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:33:46', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f' User entered '25'	System	08 Aug 2020 00:39:21

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:29:36', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f'	System	08 Aug 2020 00:39:21
User entered 'None (1)'	System	08 Aug 2020 00:39:21



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:33:58', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '2ed3d91b-5d18-44e4-bc70-8b314e569d5f'	System	08 Aug 2020 00:39:21
User entered '07 Aug 2020 18:33'	System	08 Aug 2020 00:39:21

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 3'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:30', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3354afff-06f4-455d-904f-e75e23082b24'	System	09 Aug 2020 04:14:09
User entered 'None (1)'	System	09 Aug 2020 04:14:09

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3354afff-06f4-455d-904f-e75e23082b24'	System	09 Aug 2020 04:14:09
User entered 'No (N)'	System	09 Aug 2020 04:14:09

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3354afff-06f4-455d-904f-e75e23082b24'	System	09 Aug 2020 04:14:09
User entered 'No (N)'	System	09 Aug 2020 04:14:09

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:46', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3354afff-06f4-455d-904f-e75e23082b24'	System	09 Aug 2020 04:14:09
User entered 'None (1)'	System	09 Aug 2020 04:14:09



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:14:55', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3354afff-06f4-455d-904f-e75e23082b24'	System	09 Aug 2020 04:14:09
User entered '08 Aug 2020 22:14'	System	09 Aug 2020 04:14:09

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 4'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:37', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76170766-2d0b-4765-a544-e8ede70b37da'	System	10 Aug 2020 02:08:17
User entered 'None (1)'	System	10 Aug 2020 02:08:17

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76170766-2d0b-4765-a544-e8ede70b37da'	System	10 Aug 2020 02:08:17
User entered 'No (N)'	System	10 Aug 2020 02:08:17

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76170766-2d0b-4765-a544-e8ede70b37da'	System	10 Aug 2020 02:08:17
User entered 'No (N)'	System	10 Aug 2020 02:08:17

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:08:55', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76170766-2d0b-4765-a544-e8ede70b37da'	System	10 Aug 2020 02:08:17
User entered 'None (1)'	System	10 Aug 2020 02:08:17



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:02', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76170766-2d0b-4765-a544-e8ede70b37da'	System	10 Aug 2020 02:08:17
User entered '09 Aug 2020 20:09'	System	10 Aug 2020 02:08:17

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 5'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c8dd23e7-e63e-4c86-969a-ebd9f555fd66'	System	11 Aug 2020 03:13:59
User entered 'None (1)'	System	11 Aug 2020 03:13:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:32', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c8dd23e7-e63e-4c86-969a-ebd9f555fd66'	System	11 Aug 2020 03:13:59
User entered 'No (N)'	System	11 Aug 2020 03:13:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c8dd23e7-e63e-4c86-969a-ebd9f555fd66'	System	11 Aug 2020 03:13:59
User entered 'No (N)'	System	11 Aug 2020 03:13:59

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c8dd23e7-e63e-4c86-969a-ebd9f555fd66'	System	11 Aug 2020 03:13:59
User entered 'None (1)'	System	11 Aug 2020 03:13:59



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:46', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c8dd23e7-e63e-4c86-969a-ebd9f555fd66'	System	11 Aug 2020 03:13:59
User entered '10 Aug 2020 21:14'	System	11 Aug 2020 03:13:59

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 6'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:15:52', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '4b3a499d-7088-4e37-8097-15b6eb9238ea'	System	12 Aug 2020 03:15:49
User entered 'None (1)'	System	12 Aug 2020 03:15:49

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:16:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '4b3a499d-7088-4e37-8097-15b6eb9238ea'	System	12 Aug 2020 03:15:49
User entered 'No (N)'	System	12 Aug 2020 03:15:49

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:16:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '4b3a499d-7088-4e37-8097-15b6eb9238ea'	System	12 Aug 2020 03:15:49
User entered 'No (N)'	System	12 Aug 2020 03:15:49

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:16:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '4b3a499d-7088-4e37-8097-15b6eb9238ea'	System	12 Aug 2020 03:15:49
User entered 'None (1)'	System	12 Aug 2020 03:15:49



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:16:37', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '4b3a499d-7088-4e37-8097-15b6eb9238ea'	System	12 Aug 2020 03:15:49
User entered '11 Aug 2020 21:16'	System	12 Aug 2020 03:15:49

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 7'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:16', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c7445644-0875-44a2-a700-09ddd1b6691e'	System	13 Aug 2020 06:19:47
User entered 'None (1)'	System	13 Aug 2020 06:19:47

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:20', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c7445644-0875-44a2-a700-09ddd1b6691e'	System	13 Aug 2020 06:19:47
User entered 'No (N)'	System	13 Aug 2020 06:19:47

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:22', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c7445644-0875-44a2-a700-09ddd1b6691e'	System	13 Aug 2020 06:19:47
User entered 'No (N)'	System	13 Aug 2020 06:19:47

US3142139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c7445644-0875-44a2-a700-09ddd1b6691e'	System	13 Aug 2020 06:19:47
User entered 'None (1)'	System	13 Aug 2020 06:19:47



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c7445644-0875-44a2-a700-09ddd1b6691e'	System	13 Aug 2020 06:19:47
User entered '13 Aug 2020 00:20'	System	13 Aug 2020 06:19:47

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:16:57', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:03', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:06', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:11', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'None (0)'	System	06 Aug 2020 22:16:46

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:22', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered 'No (N)'	System	06 Aug 2020 22:16:46

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-06T16:17:32', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'dc10025f-cdd4-403e-b460-51987a2086a8'	System	06 Aug 2020 22:16:46
User entered '06 Aug 2020 16:17'	System	06 Aug 2020 22:16:46

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 16:02'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 18:32'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Aug 2020 19:27'	System	06 Aug 2020 21:45:08



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 2'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:39', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:33', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:52', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:56', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:25:59', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'None (0)'	System	08 Aug 2020 00:25:35



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:26:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered 'No (N)'	System	08 Aug 2020 00:25:35

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-07T18:26:21', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fff37dbf-56aa-426b-80b1-52195f1d1f4d'	System	08 Aug 2020 00:25:35
User entered '07 Aug 2020 18:26'	System	08 Aug 2020 00:25:35

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 3'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:13', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:16', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:20', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'None (0)'	System	09 Aug 2020 04:14:54

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered 'No (N)'	System	09 Aug 2020 04:14:54

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-08T22:15:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fdab7746-e503-48c7-9b4f-2d32b178f359'	System	09 Aug 2020 04:14:54
User entered '08 Aug 2020 22:15'	System	09 Aug 2020 04:14:54

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 4'	System	06 Aug 2020 21:45:08



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d' User entered 'None (0)'	System	10 Aug 2020 02:08:57
	System	10 Aug 2020 02:08:57

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:12', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered 'None (0)'	System	10 Aug 2020 02:08:57

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:15', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered 'None (0)'	System	10 Aug 2020 02:08:57

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:19', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d' User entered 'None (0)'	System	10 Aug 2020 02:08:57
	System	10 Aug 2020 02:08:57

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:22', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered 'None (0)'	System	10 Aug 2020 02:08:57

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered 'None (0)'	System	10 Aug 2020 02:08:57

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:33', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered 'No (N)'	System	10 Aug 2020 02:08:57

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-09T20:09:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f63f0717-69bc-45a8-85b4-fc89237f317d'	System	10 Aug 2020 02:08:57
User entered '09 Aug 2020 20:09'	System	10 Aug 2020 02:08:57



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 5'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:52', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:56', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:14:58', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:15:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:15:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:15:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered 'None (0)'	System	11 Aug 2020 03:14:43

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:15:14', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered 'No (N)'	System	11 Aug 2020 03:14:43

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-10T21:15:31', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bf8fa9fe-71ad-4987-9f1c-07ae98ebee5f'	System	11 Aug 2020 03:14:43
User entered '10 Aug 2020 21:15'	System	11 Aug 2020 03:14:43

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 6'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:19', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:17:19

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'None (0)'	System	12 Aug 2020 03:17:19



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'None (0)'	System	12 Aug 2020 03:17:19

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:32', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'None (0)'	System	12 Aug 2020 03:17:19

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'None (0)'	System	12 Aug 2020 03:17:19

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'None (0)'	System	12 Aug 2020 03:17:19

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:17:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered 'No (N)'	System	12 Aug 2020 03:17:19

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-11T21:18:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c0fb6020-b347-4439-9053-bda08c4b1bf2'	System	12 Aug 2020 03:17:19
User entered '11 Aug 2020 21:18'	System	12 Aug 2020 03:17:19

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:45:08



US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 7'	System	06 Aug 2020 21:45:08

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'None (0)'	System	13 Aug 2020 06:20:29

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:51', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'None (0)'	System	13 Aug 2020 06:20:29

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:53', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'None (0)'	System	13 Aug 2020 06:20:29

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:20:57', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e' User entered 'None (0)'	System	13 Aug 2020 06:20:29
	System	13 Aug 2020 06:20:29

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:21:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'None (0)'	System	13 Aug 2020 06:20:29

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:21:03', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'None (0)'	System	13 Aug 2020 06:20:29

US3142139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:21:07', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered 'No (N)'	System	13 Aug 2020 06:20:29



**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T00:21:16', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '51865564-33ea-45e7-bcb8-c35d021a830e'	System	13 Aug 2020 06:20:29
User entered '13 Aug 2020 00:21'	System	13 Aug 2020 06:20:29

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:45:08

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	12 Aug 2020 03:14:56
User entered 'Day 8'	System	12 Aug 2020 03:14:56

US3142139

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T14:07:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '946431c1-636f-45a6-b186-5d0cae02a436'	System	13 Aug 2020 20:07:14
User entered 'No (N)'	System	13 Aug 2020 20:07:14

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-08-13T14:08:02', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '946431c1-636f-45a6-b186-5d0cae02a436'	System	13 Aug 2020 20:07:14
User entered '13 Aug 2020 14:08'	System	13 Aug 2020 20:07:14

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 03:14:56

**US3142139**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 03:14:56



**US3142139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:41:59
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:51:37

**US3142139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:41:59
User entered '14 Aug 2020'	Jill York (b) (4)	03 Sep 2020 20:51:37

**US3142139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:41:59
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	03 Sep 2020 20:51:37

US3142139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:41:59
User entered empty.	Jill York (b) (4)	03 Sep 2020 20:51:37

**US3142139**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:42:16
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:51:44

**US3142139**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	03 Sep 2020 20:51:44

**US3142139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:42:26
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:52:04

**US3142139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:01
User entered '23 Aug 2020'	Jill York (b) (4)	03 Sep 2020 20:52:04



**US3142139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:43:01
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	03 Sep 2020 20:52:04

US3142139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:01
User entered empty.	Jill York (b) (4)	03 Sep 2020 20:52:04

**US3142139**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:09
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:52:39

**US3142139**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	03 Sep 2020 20:52:39

**US3142139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:21
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:53:59

**US3142139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:21
User entered '27 Aug 2020'	Jill York (b) (4)	03 Sep 2020 20:53:59

**US3142139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:21
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	03 Sep 2020 20:53:59

US3142139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:21
User entered empty.	Jill York (b) (4)	03 Sep 2020 20:53:59



**US3142139**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:43:29
User entered 'Yes (Y)'	Jill York (b) (4)	03 Sep 2020 20:54:09

**US3142139**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	03 Sep 2020 20:54:09

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:45:50
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:33:04

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:45:54
User entered '3 Sep 2020'	Meghan York (b) (4)	11 Sep 2020 16:33:04

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:45:52
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	11 Sep 2020 16:33:04

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'VISIT2'	System	11 Sep 2020 16:33:04

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:35:10



**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '3 Sep 2020'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '14:10'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '3 Sep 2020 14:10'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '97.1' F	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'Other (Other)'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'temporal'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '63'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'bpm'	System	11 Sep 2020 16:35:10



US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '14'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'breaths/min'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '115'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '71'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:35:10



US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '3 Sep 2020'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 02:57:49
User closed query 'Please reconcile time of post dose assessment with source.' (Site from CRA).		22 Oct 2020 02:57:39
Query 'Please reconcile time of post dose assessment with source.' answered with 'done' (Site from CRA).	Meghan York (b) (4)	19 Oct 2020 17:17:05
User entered '15:39' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 17:16:59
User opened query 'Please reconcile time of post dose assessment with source.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 16:49:39
DataPoint Un-verified.		16 Oct 2020 16:48:43
DataPoint Verified.		16 Oct 2020 16:46:33
User entered '15:42'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '3 Sep 2020 15:39'	System	19 Oct 2020 17:16:59
User entered '3 Sep 2020 15:42'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '97.1' F	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'Other (Other)'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered 'temporal'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '55'	Meghan York (b) (4)	11 Sep 2020 16:35:10

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'bpm'	System	11 Sep 2020 16:35:10



US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '18'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'breaths/min'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '129'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:46:33
User entered '87'	Meghan York (b) (4)	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	11 Sep 2020 16:35:10

US3142139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:22
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:35:22

US3142139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:22
User entered '3 Sep 2020'	Meghan York (b) (4)	11 Sep 2020 16:35:22



US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered empty.	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered empty.	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered '03 Sep 2020'	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered '15:09'	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '03 Sep 2020 15:09'	System	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:50:29
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4)	04 Sep 2020 21:29:32



US3142139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
DataPoint Verified.		16 Oct 2020 16:50:29
User entered 'ONCE'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:29:32

US3142139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:11:14
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:00

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:11:14
User entered '3 Sep 2020'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:00

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:11:14
User entered '14:37'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:00

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '3 Sep 2020 14:37'	System	11 Sep 2020 16:36:00

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:26:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:51:24
User entered '3 Sep 2020'	Meghan York (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:22



**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:51:24
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:51:24
User entered '14:33'	Meghan York (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '3 Sep 2020 14:33'	System	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:51:24
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:51:24
User entered '14:33'	Meghan York (b) (4)	11 Sep 2020 16:36:22

**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '3 Sep 2020 14:33'	System	11 Sep 2020 16:36:22

US3142139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:51:37
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Sep 2020 16:36:28



**US3142139**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	11 Sep 2020 16:36:28

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 15:29'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 17:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 18:54'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 2'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:24:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '92f0d88e-ba04-4f34-8c59-b51f6cca4773'	System	05 Sep 2020 07:23:48
User entered 'Yes (Y)'	System	05 Sep 2020 07:23:48

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:24:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '92f0d88e-ba04-4f34-8c59-b51f6cca4773'	System	05 Sep 2020 07:23:48
User entered '97.8'	System	05 Sep 2020 07:23:48

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:24:37', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '92f0d88e-ba04-4f34-8c59-b51f6cca4773'	System	05 Sep 2020 07:23:48
User entered 'No (N)'	System	05 Sep 2020 07:23:48

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:24:43', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '92f0d88e-ba04-4f34-8c59-b51f6cca4773'	System	05 Sep 2020 07:23:48
User entered '05 Sep 2020 01:24'	System	05 Sep 2020 07:23:48



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 3'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:26:14', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '693566f7-5471-4c62-b90b-05affc4a0e58'	System	06 Sep 2020 01:25:49
User entered 'Yes (Y)'	System	06 Sep 2020 01:25:49

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:26:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '693566f7-5471-4c62-b90b-05affc4a0e58'	System	06 Sep 2020 01:25:49
User entered '98.4'	System	06 Sep 2020 01:25:49

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:26:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '693566f7-5471-4c62-b90b-05affc4a0e58'	System	06 Sep 2020 01:25:49
User entered 'No (N)'	System	06 Sep 2020 01:25:49

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:26:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '693566f7-5471-4c62-b90b-05affc4a0e58'	System	06 Sep 2020 01:25:49
User entered '05 Sep 2020 19:26'	System	06 Sep 2020 01:25:49

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 4'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:38:07', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '786c7afb-aae4-43ed-9b51-12400e13ab68'	System	07 Sep 2020 03:39:23
User entered 'Yes (Y)'	System	07 Sep 2020 03:39:23

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:38:15', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '786c7afb-aae4-43ed-9b51-12400e13ab68'	System	07 Sep 2020 03:39:23
User entered '98.2'	System	07 Sep 2020 03:39:23

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:38:20', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '786c7afb-aae4-43ed-9b51-12400e13ab68'	System	07 Sep 2020 03:39:23
User entered 'No (N)'	System	07 Sep 2020 03:39:23

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:40:14', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '786c7afb-aae4-43ed-9b51-12400e13ab68'	System	07 Sep 2020 03:39:23
User entered '06 Sep 2020 21:40'	System	07 Sep 2020 03:39:23

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 5'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:34:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d7b3ce-c62d-49f9-9757-463a588988e9'	System	08 Sep 2020 06:34:43
User entered 'Yes (Y)'	System	08 Sep 2020 06:34:43

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:35:33', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d7b3ce-c62d-49f9-9757-463a588988e9' User entered '97.8'	System	08 Sep 2020 06:34:43

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:35:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d7b3ce-c62d-49f9-9757-463a588988e9'	System	08 Sep 2020 06:34:43
User entered 'No (N)'	System	08 Sep 2020 06:34:43

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:35:39', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d7b3ce-c62d-49f9-9757-463a588988e9'	System	08 Sep 2020 06:34:43
User entered '08 Sep 2020 00:35'	System	08 Sep 2020 06:34:43

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 6'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:04:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bb90b9e4-efcf-4acd-b28c-1759dec4785c'	System	09 Sep 2020 12:04:16
User entered 'Yes (Y)'	System	09 Sep 2020 12:04:16

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bb90b9e4-efcf-4acd-b28c-1759dec4785c'	System	09 Sep 2020 12:04:16
User entered '98.1'	System	09 Sep 2020 12:04:16

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bb90b9e4-efcf-4acd-b28c-1759dec4785c'	System	09 Sep 2020 12:04:16
User entered 'No (N)'	System	09 Sep 2020 12:04:16

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:11', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'bb90b9e4-efcf-4acd-b28c-1759dec4785c'	System	09 Sep 2020 12:04:16
User entered '09 Sep 2020 06:05'	System	09 Sep 2020 12:04:16

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 7'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:11', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '8756fb31-852c-4221-8095-1f805f0982e9'	System	10 Sep 2020 05:31:35
User entered 'Yes (Y)'	System	10 Sep 2020 05:31:35



US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '8756fb31-852c-4221-8095-1f805f0982e9'	System	10 Sep 2020 05:31:35
User entered '98.6'	System	10 Sep 2020 05:31:35

US3142139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '8756fb31-852c-4221-8095-1f805f0982e9'	System	10 Sep 2020 05:31:35
User entered 'No (N)'	System	10 Sep 2020 05:31:35

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '8756fb31-852c-4221-8095-1f805f0982e9'	System	10 Sep 2020 05:31:35
User entered '09 Sep 2020 23:32'	System	10 Sep 2020 05:31:35

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 15:29'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 17:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 18:54'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 2'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:45', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '95ecf1d2-a9a4-4fda-a386-7664561ad722'	System	05 Sep 2020 07:17:12
User entered 'None (1)'	System	05 Sep 2020 07:17:12

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:50', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '95ecf1d2-a9a4-4fda-a386-7664561ad722'	System	05 Sep 2020 07:17:12
User entered 'No (N)'	System	05 Sep 2020 07:17:12

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:53', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '95ecf1d2-a9a4-4fda-a386-7664561ad722'	System	05 Sep 2020 07:17:12
User entered 'No (N)'	System	05 Sep 2020 07:17:12

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:58', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '95ecf1d2-a9a4-4fda-a386-7664561ad722'	System	05 Sep 2020 07:17:12
User entered 'None (1)'	System	05 Sep 2020 07:17:12

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:18:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '95ecf1d2-a9a4-4fda-a386-7664561ad722'	System	05 Sep 2020 07:17:12
User entered '05 Sep 2020 01:18'	System	05 Sep 2020 07:17:12

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:26:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 3'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:37', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '83e45817-3c74-49f4-8f0a-7e7f8a112fa0'	System	06 Sep 2020 01:25:09
User entered 'None (1)'	System	06 Sep 2020 01:25:09

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:41', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '83e45817-3c74-49f4-8f0a-7e7f8a112fa0'	System	06 Sep 2020 01:25:09
User entered 'No (N)'	System	06 Sep 2020 01:25:09

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:44', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '83e45817-3c74-49f4-8f0a-7e7f8a112fa0'	System	06 Sep 2020 01:25:09
User entered 'No (N)'	System	06 Sep 2020 01:25:09

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:54', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '83e45817-3c74-49f4-8f0a-7e7f8a112fa0'	System	06 Sep 2020 01:25:09
User entered 'None (1)'	System	06 Sep 2020 01:25:09

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:26:02', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '83e45817-3c74-49f4-8f0a-7e7f8a112fa0'	System	06 Sep 2020 01:25:09
User entered '05 Sep 2020 19:26'	System	06 Sep 2020 01:25:09

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 4'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:40:19', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a5829ac3-6679-4fad-88a3-ba81595bf018'	System	07 Sep 2020 03:40:11
User entered 'None (1)'	System	07 Sep 2020 03:40:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:40:23', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a5829ac3-6679-4fad-88a3-ba81595bf018'	System	07 Sep 2020 03:40:11
User entered 'No (N)'	System	07 Sep 2020 03:40:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:40:26', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a5829ac3-6679-4fad-88a3-ba81595bf018'	System	07 Sep 2020 03:40:11
User entered 'No (N)'	System	07 Sep 2020 03:40:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:40:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a5829ac3-6679-4fad-88a3-ba81595bf018'	System	07 Sep 2020 03:40:11
User entered 'None (1)'	System	07 Sep 2020 03:40:11

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'a5829ac3-6679-4fad-88a3-ba81595bf018'	System	07 Sep 2020 03:40:11
User entered '06 Sep 2020 21:41'	System	07 Sep 2020 03:40:11

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 5'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '141f6627-e0a3-4b03-8095-3a212d65ea5c'	System	08 Sep 2020 06:31:57
User entered 'None (1)'	System	08 Sep 2020 06:31:57

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:31', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '141f6627-e0a3-4b03-8095-3a212d65ea5c'	System	08 Sep 2020 06:31:57
User entered 'No (N)'	System	08 Sep 2020 06:31:57

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '141f6627-e0a3-4b03-8095-3a212d65ea5c'	System	08 Sep 2020 06:31:57
User entered 'No (N)'	System	08 Sep 2020 06:31:57

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '141f6627-e0a3-4b03-8095-3a212d65ea5c'	System	08 Sep 2020 06:31:57
User entered 'None (1)'	System	08 Sep 2020 06:31:57

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:51', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '141f6627-e0a3-4b03-8095-3a212d65ea5c'	System	08 Sep 2020 06:31:57
User entered '08 Sep 2020 00:32'	System	08 Sep 2020 06:31:57

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 6'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:20', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '53e151dd-0dd5-4cab-80c9-331755b7db65'	System	09 Sep 2020 12:04:52
User entered 'None (1)'	System	09 Sep 2020 12:04:52

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:24', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '53e151dd-0dd5-4cab-80c9-331755b7db65'	System	09 Sep 2020 12:04:52
User entered 'No (N)'	System	09 Sep 2020 12:04:52

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:27', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '53e151dd-0dd5-4cab-80c9-331755b7db65'	System	09 Sep 2020 12:04:52
User entered 'No (N)'	System	09 Sep 2020 12:04:52

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:35', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '53e151dd-0dd5-4cab-80c9-331755b7db65'	System	09 Sep 2020 12:04:52
User entered 'None (1)'	System	09 Sep 2020 12:04:52

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:05:47', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '53e151dd-0dd5-4cab-80c9-331755b7db65'	System	09 Sep 2020 12:04:52
User entered '09 Sep 2020 06:05'	System	09 Sep 2020 12:04:52

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 7'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:36', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5ffdbc7b-b5b2-4109-958f-0241df9e24a9'	System	10 Sep 2020 05:32:11
User entered 'None (1)'	System	10 Sep 2020 05:32:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:39', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5ffdbc7b-b5b2-4109-958f-0241df9e24a9'	System	10 Sep 2020 05:32:11
User entered 'No (N)'	System	10 Sep 2020 05:32:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5ffdbc7b-b5b2-4109-958f-0241df9e24a9'	System	10 Sep 2020 05:32:11
User entered 'No (N)'	System	10 Sep 2020 05:32:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:32:53', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5ffdbc7b-b5b2-4109-958f-0241df9e24a9'	System	10 Sep 2020 05:32:11
User entered 'None (1)'	System	10 Sep 2020 05:32:11

US3142139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:26:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5ffdbc7b-b5b2-4109-958f-0241df9e24a9'	System	10 Sep 2020 05:32:11
User entered '09 Sep 2020 23:33'	System	10 Sep 2020 05:32:11

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:26:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 15:29'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 17:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:26:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '03 Sep 2020 18:54'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 2'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:08', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:11', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:14', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:21', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'None (0)'	System	05 Sep 2020 07:16:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:26', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered 'No (N)'	System	05 Sep 2020 07:16:44

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T01:17:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c35e213a-0fd1-4796-b90e-4e2a70f77bf5'	System	05 Sep 2020 07:16:44
User entered '05 Sep 2020 01:17'	System	05 Sep 2020 07:16:44



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 3'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:24:53', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:24:56', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:24:59', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:08', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:12', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'None (0)'	System	06 Sep 2020 01:24:34

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:17', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered 'No (N)'	System	06 Sep 2020 01:24:34

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-05T19:25:27', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b6fec677-28bd-4a93-8647-f0cba8beb286'	System	06 Sep 2020 01:24:34
User entered '05 Sep 2020 19:25'	System	06 Sep 2020 01:24:34

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 4'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:32', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:36', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:45', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'None (0)'	System	07 Sep 2020 03:41:07

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:49', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered 'No (N)'	System	07 Sep 2020 03:41:07

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-06T21:41:58', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '3b57c17b-0a1a-4d3b-95d7-3aa499fe6235'	System	07 Sep 2020 03:41:07
User entered '06 Sep 2020 21:41'	System	07 Sep 2020 03:41:07

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:29:32



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 5'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:31:52', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:31:55', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:31:57', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:02', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:06', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'None (0)'	System	08 Sep 2020 06:31:29

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:12', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered 'No (N)'	System	08 Sep 2020 06:31:29



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:26:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-08T00:32:23', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ff41f30a-75f3-4a0e-8eaf-74d87cc8ba7c'	System	08 Sep 2020 06:31:29
User entered '08 Sep 2020 00:32'	System	08 Sep 2020 06:31:29

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 6'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:06:39', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:06:44', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:06:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:06:58', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:07:01', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:07:17', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'None (0)'	System	09 Sep 2020 12:06:44

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:07:23', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered 'No (N)'	System	09 Sep 2020 12:06:44

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T06:07:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ba5dbe99-33b0-4d60-a8b6-439ceddbcbde'	System	09 Sep 2020 12:06:44
User entered '09 Sep 2020 06:07'	System	09 Sep 2020 12:06:44

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	04 Sep 2020 21:29:32
User entered 'Day 7'	System	04 Sep 2020 21:29:32

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39



US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:13', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:15', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:21', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:23', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'None (0)'	System	10 Sep 2020 05:32:39

US3142139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:26:33

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)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:26', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered 'No (N)'	System	10 Sep 2020 05:32:39

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-09-09T23:33:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0568bff1-169a-4156-a21d-7b1bfbc8aadd'	System	10 Sep 2020 05:32:39
User entered '09 Sep 2020 23:33'	System	10 Sep 2020 05:32:39

**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:29:32



**US3142139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:26:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:29:32

**US3142139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:28:43
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 15:54:19

**US3142139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:28:43
User entered '11 Sep 2020'	Jill York (b) (4)	09 Oct 2020 15:54:19

**US3142139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:28:43
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	09 Oct 2020 15:54:19

US3142139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:28:43
User entered empty.	Jill York (b) (4)	09 Oct 2020 15:54:19

**US3142139**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:12:25
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 22:42:05

**US3142139**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	24 Sep 2020 22:42:05

**US3142139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:13:48
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 16:03:11



US3142139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:13:48
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		13 Oct 2020 21:39:09
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'within window' (Site from System).	Jill York (b) (4)	09 Oct 2020 16:03:18
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 16:03:11
User entered '16 Sep 2020'	Jill York (b) (4)	09 Oct 2020 16:03:11

**US3142139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:13:48
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	09 Oct 2020 16:03:11

US3142139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:13:48
User entered empty.	Jill York (b) (4)	09 Oct 2020 16:03:11

**US3142139**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:13:54
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	24 Sep 2020 22:42:13

**US3142139**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	24 Sep 2020 22:42:13

**US3142139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:54:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	24 Sep 2020 22:42:29

**US3142139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:54:34
User entered '24 Sep 2020'	Jami Wagner (b) (4)	24 Sep 2020 22:42:29

**US3142139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:54:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	24 Sep 2020 22:42:29



US3142139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:54:34
User entered empty.	Jami Wagner (b) (4)	24 Sep 2020 22:42:29

US3142139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 16:54:41
User entered 'Yes (Y)'	Jami Wagner (b) (4)	24 Sep 2020 22:42:35

**US3142139**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	24 Sep 2020 22:42:35

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:03:50
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 16:03:55

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:03:52
User entered '8 Oct 2020'	Jill York (b) (4)	09 Oct 2020 16:03:55

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:03:54
User entered 'Clinic (Clinic)'	Jill York (b) (4)	09 Oct 2020 16:03:55

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'VISIT3'	System	09 Oct 2020 16:03:55

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:04
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 16:04:38



**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:06
User entered '8 Oct 2020'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:10
User entered '13:31'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '8 Oct 2020 13:31'	System	09 Oct 2020 16:04:38

US3142139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:13
User entered '97.5' F	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:15
User entered 'Other (Other)'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:18
User entered 'temporal'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:21
User entered '56'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'bpm'	System	09 Oct 2020 16:04:38



US3142139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:24
User entered '14'	Jill York (b) (4)	09 Oct 2020 16:04:38

US3142139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'breaths/min'	System	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:30
User entered '112'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:04:32
User entered '73'	Jill York (b) (4)	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'mmHg'	System	09 Oct 2020 16:04:38

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17



US3142139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User closed query 'Please verify if subject had a procedure associated with the "broken arm"' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:06:37
User closed query 'Please verify if "broken arm" as noted in 08/Oct progress notes should be added as an AE' (Site from CRA).		20 Apr 2021 23:06:20
User signature succeeded.		
	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
	(b) (4)	
Query 'Please verify if "broken arm" as noted in 08/Oct progress notes should be added as an AE' answered with 'fractured right wrist added' (Site from CRA).	Jill York (b) (4)	15 Apr 2021 00:02:29
Query 'Please verify if subject had a procedure associated with the "broken arm"' answered with 'No procedure' (Site from CRA).	Shelby Pickle (b) (4)	31 Mar 2021 20:02:41
	(b) (4)	
User opened query 'Please verify if subject had a procedure associated with the "broken arm"' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 19:01:44
User opened query 'Please verify if "broken arm" as noted in 08/Oct progress notes should be added as an AE' (Site from CRA).		15 Dec 2020 18:50:15
DataPoint Verified.		29 Oct 2020 16:04:45
User entered 'Yes (Y)'		
	Jill York (b) (4)	09 Oct 2020 16:04:48

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:48
User entered '8 Oct 2020'	Jill York (b) (4)	09 Oct 2020 16:04:48

US3142139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:05:07
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 16:05:01

US3142139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 05:54:23
		29 Oct 2020 16:05:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' answered with 'Information is correct. Unscheduled lab kit was used for this visit due to lack of supplies ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 15:32:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:57:14
User entered '8 Oct 2020'	Jill York (b) (4)	09 Oct 2020 16:05:01

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:05:12
User entered '13:38'	Jill York (b) (4)	09 Oct 2020 16:05:01

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered '8 Oct 2020 13:38'	System	09 Oct 2020 16:05:01

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:05:21
User entered 'Yes (Y)'	Jill York (b) (4)	09 Oct 2020 16:05:10

**US3142139**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	09 Oct 2020 16:05:10



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 64'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 71'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-10-16T09:41:28', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '318131f8-bf62-434e-8749-4f1144bf9924'	System	16 Oct 2020 15:41:50
User entered 'No (N)'	System	16 Oct 2020 15:41:50

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-10-16T09:41:34', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '318131f8-bf62-434e-8749-4f1144bf9924'	System	16 Oct 2020 15:41:50
User entered 'No (N)'	System	16 Oct 2020 15:41:50

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-10-16T09:41:44', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '318131f8-bf62-434e-8749-4f1144bf9924' User entered '16 Oct 2020 09:41:44'	System	16 Oct 2020 15:41:50
	System	16 Oct 2020 15:41:50



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 78'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 92'	System	06 Aug 2020 21:45:08

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-06T22:42:07', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76d52d12-293a-4069-a7f5-2216c3c115ac'	System	07 Nov 2020 05:42:25
User entered 'No (N)'	System	07 Nov 2020 05:42:25



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-06T22:42:13', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76d52d12-293a-4069-a7f5-2216c3c115ac'	System	07 Nov 2020 05:42:25
User entered 'No (N)'	System	07 Nov 2020 05:42:25

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-06T22:42:27', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '76d52d12-293a-4069-a7f5-2216c3c115ac'	System	07 Nov 2020 05:42:25
User entered '06 Nov 2020 22:42:27'	System	07 Nov 2020 05:42:25

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 99'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:16:16
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 21:45:08



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered 'Day 106'	System	06 Aug 2020 21:45:08

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-18T20:19:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9fd2f9c1-f45a-4cfc-b434-564c91ecbb5e'	System	19 Nov 2020 03:19:35
User entered 'No (N)'	System	19 Nov 2020 03:19:35

US3142139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:26:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-18T20:19:30', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9fd2f9c1-f45a-4cfc-b434-564c91ecbb5e'	System	19 Nov 2020 03:19:35
User entered 'No (N)'	System	19 Nov 2020 03:19:35

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-11-18T20:19:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9fd2f9c1-f45a-4cfc-b434-564c91ecbb5e'	System	19 Nov 2020 03:19:35
User entered '18 Nov 2020 20:19:38'	System	19 Nov 2020 03:19:35

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:47:40
Data entry locked.	System	06 Aug 2020 21:45:08
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 21:45:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2020-12-09T19:24:36', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '1256a2fe-a007-4584-aa58-9cc2f423ed88'	System	10 Dec 2020 02:24:49
User entered 'No (N)'	System	10 Dec 2020 02:24:49

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2020-12-09T19:24:54', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '1256a2fe-a007-4584-aa58-9cc2f423ed88'	System	10 Dec 2020 02:24:49
User entered 'No (N)'	System	10 Dec 2020 02:24:49

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-12-09T19:24:59', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '1256a2fe-a007-4584-aa58-9cc2f423ed88'	System	10 Dec 2020 02:24:49
User entered '09 Dec 2020 19:24:59'	System	10 Dec 2020 02:24:49



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:16:16

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:16:16

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:16:16

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2020-12-21T05:58:48', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '522a2678-571b-437e-85ea-2d8c4c10f6f6'	System	21 Dec 2020 12:58:44
User entered 'No (N)'	System	21 Dec 2020 12:58:44

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2020-12-21T05:58:53', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '522a2678-571b-437e-85ea-2d8c4c10f6f6'	System	21 Dec 2020 12:58:44
User entered 'No (N)'	System	21 Dec 2020 12:58:44



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-12-21T05:58:59', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '522a2678-571b-437e-85ea-2d8c4c10f6f6'	System	21 Dec 2020 12:58:44
User entered '21 Dec 2020 05:58:59'	System	21 Dec 2020 12:58:44

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2020-12-28T18:28:09', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fbded51e-688d-4338-a907-9c804869585b'	System	29 Dec 2020 01:28:08
User entered 'No (N)'	System	29 Dec 2020 01:28:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2020-12-28T18:28:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fbded51e-688d-4338-a907-9c804869585b'	System	29 Dec 2020 01:28:08
User entered 'No (N)'	System	29 Dec 2020 01:28:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2020-12-28T18:28:26', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'fbded51e-688d-4338-a907-9c804869585b'	System	29 Dec 2020 01:28:08
User entered '28 Dec 2020 18:28:26'	System	29 Dec 2020 01:28:08

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-01-26T00:46:54', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d1a98c-0422-4cd8-92bb-59948662f81e'	System	26 Jan 2021 07:46:39
User entered 'No (N)'	System	26 Jan 2021 07:46:39

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-01-26T00:46:59', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d1a98c-0422-4cd8-92bb-59948662f81e'	System	26 Jan 2021 07:46:39
User entered 'No (N)'	System	26 Jan 2021 07:46:39

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-01-26T00:47:05', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '01d1a98c-0422-4cd8-92bb-59948662f81e' User entered '26 Jan 2021 00:47:05'	System	26 Jan 2021 07:46:39

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-02-02T02:05:08', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '37f52298-aafa-45c2-81fc-70358326ef9d'	System	02 Feb 2021 09:04:59
User entered 'No (N)'	System	02 Feb 2021 09:04:59

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-02-02T02:05:18', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '37f52298-aafa-45c2-81fc-70358326ef9d'	System	02 Feb 2021 09:04:59
User entered 'No (N)'	System	02 Feb 2021 09:04:59

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-02T02:05:25', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '37f52298-aafa-45c2-81fc-70358326ef9d'	System	02 Feb 2021 09:04:59
User entered '02 Feb 2021 02:05:25'	System	02 Feb 2021 09:04:59

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-02-08T23:39:57', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '36178e81-e5fc-486c-bb95-3ff15ff9d483'	System	09 Feb 2021 06:40:00
User entered 'No (N)'	System	09 Feb 2021 06:40:00



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-02-08T23:40:04', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '36178e81-e5fc-486c-bb95-3ff15ff9d483'	System	09 Feb 2021 06:40:00
User entered 'No (N)'	System	09 Feb 2021 06:40:00

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-08T23:40:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '36178e81-e5fc-486c-bb95-3ff15ff9d483'	System	09 Feb 2021 06:40:00
User entered '08 Feb 2021 23:40:29'	System	09 Feb 2021 06:40:00

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-02-15T10:43:38', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c50417e7-54ce-4e26-95cd-61236abb170e'	System	15 Feb 2021 17:43:17
User entered 'No (N)'	System	15 Feb 2021 17:43:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-02-15T10:43:42', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c50417e7-54ce-4e26-95cd-61236abb170e'	System	15 Feb 2021 17:43:17
User entered 'No (N)'	System	15 Feb 2021 17:43:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-15T10:43:49', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'c50417e7-54ce-4e26-95cd-61236abb170e' User entered '15 Feb 2021 10:43:49'	System	15 Feb 2021 17:43:17
	System	15 Feb 2021 17:43:17



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-02-22T23:58:29', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '07bae43a-a59a-4ecd-87e8-ff5706b481b8'	System	23 Feb 2021 06:58:05
User entered 'No (N)'	System	23 Feb 2021 06:58:05

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-02-22T23:58:35', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '07bae43a-a59a-4ecd-87e8-ff5706b481b8'	System	23 Feb 2021 06:58:05
User entered 'No (N)'	System	23 Feb 2021 06:58:05

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-22T23:58:40', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '07bae43a-a59a-4ecd-87e8-ff5706b481b8'	System	23 Feb 2021 06:58:05
User entered '22 Feb 2021 23:58:40'	System	23 Feb 2021 06:58:05

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-02-27T12:56:44-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0cfc1f2e-32b1-4fd8-a68a-c0d595512160'	System	27 Feb 2021 19:56:21
User entered 'No (N)'	System	27 Feb 2021 19:56:21

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-02-27T12:56:49-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0cfc1f2e-32b1-4fd8-a68a-c0d595512160'	System	27 Feb 2021 19:56:21
User entered 'No (N)'	System	27 Feb 2021 19:56:21

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-27T12:56:54-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '0cfc1f2e-32b1-4fd8-a68a-c0d595512160' User entered '27 Feb 2021 12:56:54'	System	27 Feb 2021 19:56:21
	System	27 Feb 2021 19:56:21

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-03-13T21:02:43-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9f1f37ca-dc97-40c6-813c-f0237320223b'	System	14 Mar 2021 04:04:12
User entered 'No (N)'	System	14 Mar 2021 04:04:12

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-03-13T21:03:00-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9f1f37ca-dc97-40c6-813c-f0237320223b'	System	14 Mar 2021 04:04:12
User entered 'No (N)'	System	14 Mar 2021 04:04:12

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-03-13T21:04:54-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9f1f37ca-dc97-40c6-813c-f0237320223b' User entered '13 Mar 2021 21:04:54'	System	14 Mar 2021 04:04:12

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-03-24T08:45:39-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b3bcc916-37a3-482d-b0ee-921b82343e20'	System	24 Mar 2021 14:46:02
User entered 'No (N)'	System	24 Mar 2021 14:46:02

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-03-24T08:45:46-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b3bcc916-37a3-482d-b0ee-921b82343e20'	System	24 Mar 2021 14:46:02
User entered 'No (N)'	System	24 Mar 2021 14:46:02

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-03-24T08:45:54-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'b3bcc916-37a3-482d-b0ee-921b82343e20' User entered '24 Mar 2021 08:45:54'	System	24 Mar 2021 14:46:02
	System	24 Mar 2021 14:46:02

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-03-29T12:44:13-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '38e297d7-7c1d-4d3e-a848-1416bc29fa3e'	System	29 Mar 2021 18:44:28
User entered 'No (N)'	System	29 Mar 2021 18:44:28

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-03-29T12:44:17-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '38e297d7-7c1d-4d3e-a848-1416bc29fa3e'	System	29 Mar 2021 18:44:28
User entered 'No (N)'	System	29 Mar 2021 18:44:28



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-03-29T12:44:22-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '38e297d7-7c1d-4d3e-a848-1416bc29fa3e' User entered '29 Mar 2021 12:44:22'	System	29 Mar 2021 18:44:28
	System	29 Mar 2021 18:44:28

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (e84293e11a9240ba)', Time: '2021-04-04T08:26:07-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9cb6dd97-8c01-4fbb-8c50-6820fabefc53'	System	04 Apr 2021 14:26:17
User entered 'No (N)'	System	04 Apr 2021 14:26:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (e84293e11a9240ba)', Time: '2021-04-04T08:26:11-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9cb6dd97-8c01-4fbb-8c50-6820fabefc53'	System	04 Apr 2021 14:26:17
User entered 'No (N)'	System	04 Apr 2021 14:26:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-04-04T08:26:15-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '9cb6dd97-8c01-4fbb-8c50-6820fabefc53'	System	04 Apr 2021 14:26:17
User entered '04 Apr 2021 08:26:15'	System	04 Apr 2021 14:26:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-04-10T07:06:56-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6ea88361-4891-4fe7-a45c-0e0f3d1a8389'	System	10 Apr 2021 13:07:17
User entered 'No (N)'	System	10 Apr 2021 13:07:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (eb3a97519dcd5f2b)', Time: '2021-04-10T07:07:02-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6ea88361-4891-4fe7-a45c-0e0f3d1a8389'	System	10 Apr 2021 13:07:17
User entered 'No (N)'	System	10 Apr 2021 13:07:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eb3a97519dcd5f2b)', Time: '2021-04-10T07:07:05-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '6ea88361-4891-4fe7-a45c-0e0f3d1a8389'	System	10 Apr 2021 13:07:17
User entered '10 Apr 2021 07:07:05'	System	10 Apr 2021 13:07:17

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-04-17T07:12:14-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f305800f-1552-467d-b071-8cdbdc64c53b'	System	17 Apr 2021 13:12:37
User entered 'Yes (Y)'	System	17 Apr 2021 13:12:37

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (eb3a97519dcd5f2b)', Time: '2021-04-17T07:12:17-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f305800f-1552-467d-b071-8cdbdc64c53b'	System	17 Apr 2021 13:12:37
User entered 'No (N)'	System	17 Apr 2021 13:12:37

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-04-17T07:12:22-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f305800f-1552-467d-b071-8cdbdc64c53b'	System	17 Apr 2021 13:12:37
User entered 'No (N)'	System	17 Apr 2021 13:12:37

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-04-17T07:12:31-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f305800f-1552-467d-b071-8cdbdc64c53b'	System	17 Apr 2021 13:12:37
User entered 'No (N)'	System	17 Apr 2021 13:12:37

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eb3a97519dcd5f2b)', Time: '2021-04-17T07:12:35-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'f305800f-1552-467d-b071-8cdbdc64c53b' User entered '17 Apr 2021 07:12:35'	System	17 Apr 2021 13:12:37
	System	17 Apr 2021 13:12:37

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:16:16



**US3142139**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-04-24T18:10:40-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ca989418-7e86-4e9b-93cf-fa7137367220'	System	25 Apr 2021 00:10:55
User entered 'No (N)'	System	25 Apr 2021 00:10:55

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (eb3a97519dcd5f2b)', Time: '2021-04-24T18:10:44-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ca989418-7e86-4e9b-93cf-fa7137367220'	System	25 Apr 2021 00:10:55
User entered 'No (N)'	System	25 Apr 2021 00:10:55

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eb3a97519dcd5f2b)', Time: '2021-04-24T18:10:47-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: 'ca989418-7e86-4e9b-93cf-fa7137367220'	System	25 Apr 2021 00:10:55
User entered '24 Apr 2021 18:10:47'	System	25 Apr 2021 00:10:55

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[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 (eb3a97519dcd5f2b)', Time: '2021-05-01T02:49:37-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '85a1f5f9-b304-4e9a-9b60-0d5a8e5d45d5'	System	01 May 2021 08:50:07
User entered 'No (N)'	System	01 May 2021 08:50:07

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

Have you been exposed to someone with 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 (eb3a97519dcd5f2b)', Time: '2021-05-01T02:50:01-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '85a1f5f9-b304-4e9a-9b60-0d5a8e5d45d5'	System	01 May 2021 08:50:07
User entered 'No (N)'	System	01 May 2021 08:50:07



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eb3a97519dcd5f2b)', Time: '2021-05-01T02:50:04-06:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '85a1f5f9-b304-4e9a-9b60-0d5a8e5d45d5'	System	01 May 2021 08:50:07
User entered '01 May 2021 02:50:04'	System	01 May 2021 08:50:07

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:16:16



**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:16:16

**US3142139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:26:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:16:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:16:16

US3142139

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:26:33**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-27T12:57:52-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5acf5035-8ca1-413d-a795-e63f761bfdc9'	System	27 Feb 2021 19:57:28
User entered 'Yes (Y)'	System	27 Feb 2021 19:57:28

US3142139

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:26:33**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-27T12:57:54-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5acf5035-8ca1-413d-a795-e63f761bfdc9'	System	27 Feb 2021 19:57:28
User entered 'No (N)'	System	27 Feb 2021 19:57:28

**US3142139**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:01:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e84293e11a9240ba)', Time: '2021-02-27T12:57:58-07:00', User OID: 'PatientReportedOutcome (US3142139)', ODM File OID: '5acf5035-8ca1-413d-a795-e63f761bfdc9' User entered '27 Feb 2021 12:57:58'	System	27 Feb 2021 19:57:28
	System	27 Feb 2021 19:57:28

**US3142139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 19:03:44
User entered 'Yes (Y)'	Jami Wagner (b) (4)	02 Nov 2020 18:42:44



**US3142139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 19:03:46
User entered '28 Oct 2020'	Jami Wagner (b) (4)	02 Nov 2020 18:42:44

**US3142139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 19:03:47
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	02 Nov 2020 18:42:44

US3142139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:30:43
Protocol deviation created: Please verify if surgery should be added to Concomitant procedure page. There is an entry for Dental Surgery but for an earlier time frame. Class: Incl/Excl Criteria not met Code: Deviation.		15 Dec 2020 21:24:34
Query 'Please if surgery should be added to Concomitant procedure page. There is an entry for Dental Surgery but for an earlier time frame. ' canceled (Site from CRA).		15 Dec 2020 21:24:09
User opened query 'Please if surgery should be added to Concomitant procedure page. There is an entry for Dental Surgery but for an earlier time frame. ' (Site from CRA).		15 Dec 2020 18:58:21
User closed query 'Per DM CLR: Comment = PT TAKING HYDROCODONE PRO POST SURGERY. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).		04 Dec 2020 03:47:43
Query 'Per DM CLR: Comment = PT TAKING HYDROCODONE PRO POST SURGERY. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' answered with 'now added ' (Site from DM).		
User opened query 'Per DM CLR: Comment = PT TAKING HYDROCODONE PRO POST SURGERY. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:14
User opened query 'Per DM CLR: Comment = PT TAKING HYDROCODONE PRO POST SURGERY. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:00:22
User entered 'pt taking hydrocodone pro post surgery, pt to report start date, surgery details and dosage once she is at home an can review.'	Jami Wagner (b) (4) (b) (4)	02 Nov 2020 18:42:44

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3142139**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 18:41:32
User entered 'Yes (Y)'	Jami Wagner (b) (4)	02 Nov 2020 18:42:51

**US3142139**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:17
User entered 'I'	System	02 Nov 2020 18:42:51

**US3142139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:56:08
User entered 'Yes (Y)'	Jami Wagner (b) (4)	30 Nov 2020 23:02:13

**US3142139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:56:08
User entered '30 Nov 2020'	Jami Wagner (b) (4)	30 Nov 2020 23:02:13

**US3142139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:56:08
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	30 Nov 2020 23:02:13



US3142139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:56:08
User entered empty.	Jami Wagner (b) (4)	30 Nov 2020 23:02:13

**US3142139**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:14:59
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	01 Dec 2020 22:25:30

**US3142139**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User entered 'I'	System	01 Dec 2020 22:25:30

**US3142139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:15:32
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:58:43

US3142139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:15:32
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		23 Jan 2021 00:10:44
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	21 Jan 2021 18:47:26
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 20:58:43
User entered '5 Jan 2021'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:58:43

**US3142139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:15:32
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	06 Jan 2021 20:58:43

US3142139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:15:32
User entered empty.	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:58:43

**US3142139**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:15:38
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	06 Jan 2021 20:58:47



**US3142139**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User entered 'I'	System	06 Jan 2021 20:58:47

**US3142139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:20:24
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:16:35

US3142139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 20:20:24
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		11 Feb 2021 20:02:38
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'information is correct ' (Site from System).	Jill York (b) (4)	03 Feb 2021 17:29:42
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Feb 2021 22:16:35
User entered '27 Jan 2021'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:16:35

**US3142139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:20:24
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	01 Feb 2021 22:16:35

**US3142139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:20:24
User entered empty.	Jami Wagner (b) (4)	01 Feb 2021 22:16:35

**US3142139**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:31:23
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:16:40

**US3142139**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:29:17
User entered 'I'	System	01 Feb 2021 22:16:40

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:50:38
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 19:04:26



**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:50:38
User entered '4 Mar 2021'	Jill York (b) (4)	11 Mar 2021 19:04:26

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[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 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:50:38
User entered 'Clinic (Clinic)'	Jill York (b) (4)	11 Mar 2021 19:04:26

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered 'VISIT4'	System	11 Mar 2021 19:04:26

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered 'No (N)'	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered empty.	System	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46



**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered empty.	System	05 Apr 2021 21:56:46

US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered empty.	System	05 Apr 2021 21:56:46

US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered empty.	System	05 Apr 2021 21:56:46



US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:34:23
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered empty.	System	05 Apr 2021 21:56:46

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:26:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07

US3142139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:26:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07

US3142139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:50:52
User entered 'No (N)'	Jill York (b) (4)	11 Mar 2021 19:04:33

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:50:54
User entered empty.	Jill York (b) (4)	11 Mar 2021 19:04:33

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:51:01
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 19:04:54

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:51:01
User entered '4 Mar 2021'	Jill York (b) (4)	11 Mar 2021 19:04:54



**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:51:01
User entered '15:03'	Jill York (b) (4)	11 Mar 2021 19:04:54

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered '4 Mar 2021 15:03'	System	11 Mar 2021 19:04:54

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:51:06
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 19:05:00

**US3142139**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:08:07
User entered 'I'	System	11 Mar 2021 19:05:00

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:26:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:07
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:35:34

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:26:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:07
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:35:34

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[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 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:07
User entered 'Clinic (Clinic)'	Jill York (b) (4)	03 Feb 2021 19:35:34

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 19:35:34



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:33**

[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 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:42:42
User entered '0'	Jami Wagner (b) (4)	09 Apr 2021 18:38:52
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:47:13

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:36:11

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:08:02
		14 Apr 2021 17:42:46
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 18:39:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 18:38:52
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	09 Apr 2021 17:13:37
	System	06 Mar 2021 11:47:13

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:36:11

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered 'Placebo (Placebo)'	Jill York (b) (4)	03 Feb 2021 19:36:11

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered 'Placebo (Placebo)'	Jill York (b) (4)	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:33**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered 'Placebo (Placebo)'	Jill York (b) (4)	03 Feb 2021 19:36:11



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:26:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:17:46
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:33**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:07
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:11
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28
DataPoint set to visible.	System	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:07
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:11
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28



**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:26:33**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28
DataPoint set to visible.	System	03 Feb 2021 19:36:11

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '14:02'	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '28 Jan 2021 14:02'	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Feb 2021 19:40:13
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Jill York (b) (4)	03 Feb 2021 19:37:37
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Feb 2021 19:37:28
User entered '96.4' F	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered 'Other (Other)'	Jill York (b) (4)	03 Feb 2021 19:37:28



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered 'temporal'	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '58'	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'bpm'	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '12'	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'breaths/min'	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '151'	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:26:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered '76'	Jill York (b) (4)	03 Feb 2021 19:37:28



**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:07
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:11
User entered missing code ND - Not Done.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:26:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28
DataPoint set to visible.	System	03 Feb 2021 19:36:11

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered 'No (N)'	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28



**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:18:36
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:37:28

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered empty.	System	03 Feb 2021 19:37:28

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:38
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:37:57

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:26:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:38
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:37:57

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:38:32

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:38:32



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

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 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered empty.	Jill York (b) (4)	03 Feb 2021 19:38:32

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mRNA-1273'	System	03 Feb 2021 19:38:32
DataPoint set to visible.	System	03 Feb 2021 19:36:11

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:38:32

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered '15:38'	Jill York (b) (4)	03 Feb 2021 19:38:32

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '28 Jan 2021 15:38'	System	03 Feb 2021 19:38:32

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:28:05
User entered 'Right Arm (RIGHT ARM)'	Jill York (b) (4)	03 Feb 2021 19:38:32

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
DataPoint Verified.		31 Mar 2021 17:28:05
User entered 'ONCE'	System	03 Feb 2021 19:38:32

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 19:38:32



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:22
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).		24 Feb 2021 11:05:38
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 shipped, however, accession number and tracking detail cannot be provided. ' (Site from DM).	Jill York (b) (4)	11 Feb 2021 17:43:05
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)	11 Feb 2021 16:21:27
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:39:36

US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:26:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:22
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:39:36

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:22
User entered '13:57'	Jill York (b) (4)	03 Feb 2021 19:39:36

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '28 Jan 2021 13:57'	System	03 Feb 2021 19:39:36

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:29
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:39:56

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:29
User entered '28 Jan 2021'	Jill York (b) (4)	03 Feb 2021 19:39:56

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:29
User entered '13:58'	Jill York (b) (4)	03 Feb 2021 19:39:56

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:26:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '28 Jan 2021 13:58'	System	03 Feb 2021 19:39:56



US3142139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:26:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:35
User entered 'Yes (Y)'	Jill York (b) (4)	03 Feb 2021 19:40:05

**US3142139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	03 Feb 2021 19:40:05

**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:42:14
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:09

US3142139

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:42:14
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).		11 Mar 2021 14:42:21
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 'data entered is correct ' (Site from System).	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:47
User opened 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).	System	09 Mar 2021 22:35:09
User entered '8 Mar 2021'	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:09

**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:42:14
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:09

**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:42:14
User entered empty.	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:09

**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:43:31
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	09 Mar 2021 22:35:59

**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	09 Mar 2021 22:35:59



**US3142139**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '1'	System	09 Mar 2021 22:35:59
DataPoint set to visible.	System	09 Mar 2021 22:35:59

US3142139

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:26:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User closed query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 04MAR2021 Barcode: 1F623314623 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 11:50:59
	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
	(b) (4)	
Query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 04MAR2021 Barcode: 1F623314623 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' answered with 'information is EDC is correct. Perclarus queries cannot be addressed in EDC' (Site from DM). DataPoint Verified.	Jill York (b) (4)	13 Apr 2021 17:56:00
	(b) (4), (b) (6)	31 Mar 2021 17:44:01
User opened query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 04MAR2021 Barcode: 1F623314623 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 11:02:26
	Lisa Jackson (b) (4)	09 Mar 2021 22:50:43
	(b) (4)	

**US3142139**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:44:01
User entered '04 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:50:43

**US3142139**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[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 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:44:01
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:50:43

**US3142139**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:26:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'OLD29'	System	09 Mar 2021 22:50:43

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '04 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56



**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '14:44'	Lisa Jackson (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '04 Mar 2021 14:44'	System	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '97.6' F	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Temporal'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '80'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'bpm'	System	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '14'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56



**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'breaths/min'	System	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '115'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '86'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:54:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	09 Mar 2021 22:54:56

US3142139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '04 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09



**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '15:50'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '04 Mar 2021 15:50'	System	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '96.8' F	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered 'Temporal'	Lisa Jackson (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '68'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'bpm'	System	09 Mar 2021 23:03:09

US3142139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:26:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '10'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09



**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'breaths/min'	System	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '122'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:25
User entered '75'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mmHg'	System	09 Mar 2021 23:03:09

**US3142139**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:37
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:52:50

**US3142139**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:26:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:45:37
User entered '04 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:52:50

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:46:11
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	09 Mar 2021 22:51:42



**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:46:11
User entered empty.	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:51:42

US3142139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

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 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:46:11
User entered empty.	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:51:42

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'mRNA-1273'	System	09 Mar 2021 22:51:42
DataPoint set to visible.	System	09 Mar 2021 22:35:59

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:46:11
User entered '04 Mar 2021'	Lisa Jackson (b) (4)	09 Mar 2021 22:51:42

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:46:11
User entered '15:20'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:51:42

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered '04 Mar 2021 15:20'	System	09 Mar 2021 22:51:42

US3142139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:26:33

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:46:11
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		11 Mar 2021 14:44:14
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'stated as documented' (Site from System).	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:52:14
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	09 Mar 2021 22:51:42
User entered 'Left Arm (LEFT ARM)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:51:42

**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
DataPoint Verified.		31 Mar 2021 17:46:11
User entered 'ONCE'	System	09 Mar 2021 22:51:42



**US3142139**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:26:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 22:51:42

**US3142139**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:46:19
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	09 Mar 2021 22:50:56

**US3142139**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	09 Mar 2021 22:50:56

**US3142139**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:22
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:36:50

US3142139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:26:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:22
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).		02 Apr 2021 07:28:06
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 'data is as documented' (Site from System).	Lisa Jackson (b) (4)	31 Mar 2021 22:37:11
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	31 Mar 2021 22:36:50
User entered '08 Mar 2021'	Lisa Jackson (b) (4)	31 Mar 2021 22:36:50

**US3142139**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:22
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	31 Mar 2021 22:36:50

**US3142139**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:26:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:39:22
User entered empty.	Lisa Jackson (b) (4) (b) (4)	31 Mar 2021 22:36:50

**US3142139**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:41:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 22:37:21



**US3142139**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:26:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:19
User entered 'I'	System	31 Mar 2021 22:37:21

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:26:33**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:33
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:18:00
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	28 Jan 2021 17:38:14

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
Reviewed for Safety.		07 Apr 2021 21:50:30
User entered 'USA-US064-2021-mRNA-1273-P301000010'	System	07 Apr 2021 21:48:32
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 21:48:32

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'PV Query: Event is reported as Hospitalization due to a kidney stone, please consider reporting event term as condition only.' (Site from Safety).		20 Apr 2021 11:53:49
Query 'PV Query: Event is reported as Hospitalization due to a kidney stone, please consider reporting event term as condition only.' answered with 'term is correct' (Site from Safety).	Jill York (b) (4)	19 Apr 2021 17:29:26
User opened query 'PV Query: Event is reported as Hospitalization due to a kidney stone, please consider reporting event term as condition only.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:08:42
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:00:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:00:38
Data point term sent to Coder	System	07 Apr 2021 15:56:32
User entered 'hospitalization due to a kidney stone'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Yes (Y)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '2 Apr 2021'	Jill York (b) (4)	07 Apr 2021 15:55:59



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '4 Apr 2021'	Jill York (b) (4)	07 Apr 2021 15:55:59

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jill York (b) (4)	07 Apr 2021 15:55:59

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 15:56:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 15:55:59
User entered 'Yes (Y)'	Jill York (b) (4)	07 Apr 2021 15:55:59



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		07 Apr 2021 15:56:34
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		07 Apr 2021 15:56:34
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	07 Apr 2021 15:56:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 15:55:59
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '2 Apr 2021'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '4 Apr 2021'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	07 Apr 2021 15:55:59

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'PV Query: Please update action taken from none to not applicable as subject received both scheduled doses of study drug.' (Site from Safety).		19 Apr 2021 15:27:50
Query 'PV Query: Please update action taken from none to not applicable as subject received both scheduled doses of study drug.' answered with 'corrected ' (Site from Safety).	Jill York (b) (4)	16 Apr 2021 16:07:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jill York (b) (4)	16 Apr 2021 16:06:52
User opened query 'PV Query: Please update action taken from none to not applicable as subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:09:05
User entered 'None (NONE)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'I'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'I'	Jill York (b) (4)	07 Apr 2021 15:55:59



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	07 Apr 2021 15:55:59

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As subject was reported taking pain medications for dental surgery, please consider adding "dental surgery" subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 20:57:14
User closed query 'PV Query: As subject was reported taking pain medications for dental surgery, please consider adding to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:16:52
User closed query 'PV Query: Please confirm if hydrocodone is ongoing from past dental surgery.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:16:49
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:16:44
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'subject denies COVID-19 testing' (Site from Safety).	Jill York (b) (4)	21 Apr 2021 19:09:49
Query 'PV Query: As subject was reported taking pain medications for dental surgery, please consider adding to subject's medical history.' answered with 'what is to be added to medical history?' (Site from Safety).	Jill York (b) (4)	21 Apr 2021 19:09:10
Query 'PV Query: Please confirm if hydrocodone is ongoing from past dental surgery.' answered with 'not from past dental surgery' (Site from Safety).	Jill York (b) (4)	21 Apr 2021 19:08:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User opened query 'PV Query: As subject was reported taking pain medications for dental surgery, please consider adding to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:09:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:09:33

US3142139

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:26:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:09:25
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		15 Apr 2021 23:09:14
User opened query 'PV Query: Please confirm if hydrocodone is ongoing from past dental surgery.' (Site from Safety).		15 Apr 2021 23:08:53
User entered 'Subject hospitalized overnight due to kidney stone'	Jill York (b) (4)	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 15:55:59

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 15:55:59

US3142139

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Broken wrist - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 23:57:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 23:57:05
Data point term sent to Coder	System	14 Apr 2021 23:55:55
User entered 'right broken wrist'	Jill York (b) (4)	14 Apr 2021 23:55:48



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Yes (Y)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	14 Apr 2021 23:55:48

US3142139

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 16:07:57
User entered '10 Sep 2020' reason for change: Data Entry Error	Jill York (b) (4)	16 Apr 2021 16:07:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 15:57:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 15:57:18
User entered ' Sep 2020' (non-conformant).	Jami Wagner (b) (4)	16 Apr 2021 15:57:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Apr 2021 23:55:48
User entered 'un Sep 2020' (non-conformant).	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	14 Apr 2021 23:55:48

US3142139

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:26:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 16:07:57
User entered '10 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	16 Apr 2021 16:07:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 15:57:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Apr 2021 15:57:18
User entered '10 Dec 2020' (non-conformant).	Jami Wagner (b) (4)	16 Apr 2021 15:57:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Apr 2021 23:55:48
User entered '10 Dec 2020' (non-conformant).	Jill York (b) (4)	14 Apr 2021 23:55:48



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'No (N)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Related (RELATED)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Related (RELATED)'	Jill York (b) (4)	14 Apr 2021 23:55:48



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'None (NONE)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered '0'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'I'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'I'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:39:47
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:55:48

**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 23:55:48



**US3142139**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 23:55:48

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:26:33

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:00:01
User signature succeeded.	Ripley Hollister (b) (4)	03 May 2021 15:03:33
User closed query 'Per ETRTR: According to SAE "Hospitalization due to Kidney Stone", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 23:55:37
User closed query 'Please add last 2 meds listed on con med source if agreed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:00:00
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:52:35
Query 'Please add last 2 meds listed on con med source if agreed.' answered with 'added both conmeds per source' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:52:19
Query 'Per ETRTR: According to SAE "Hospitalization due to Kidney Stone", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'site does not medical records yet. will update as soon as site receives records' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:46:51
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'subject had facial fillers done 10 years ago' (Site from DM).	Jill York (b) (4)	14 Apr 2021 23:46:06

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:26:33

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Please add last 2 meds listed on con med source if agreed.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:26:51
		14 Apr 2021 17:21:44
User opened query 'Per ETRTR: According to SAE "Hospitalization due to Kidney Stone", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).		09 Apr 2021 15:24:28
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).		23 Mar 2021 08:51:51
User closed query 'Per CDM RQ: Query response on Diary Dose 1(1), Temperature Log Line 7 noted. Per the participant response, medication was taken to treat pain or fever. Please reconcile and update to record the medication given as appropriate on ConMed eCRF page, otherwise clarify. ' (Site from DM).		11 Dec 2020 05:04:25
Query 'Per CDM RQ: Query response on Diary Dose 1(1), Temperature Log Line 7 noted. Per the participant response, medication was taken to treat pain or fever. Please reconcile and update to record the medication given as appropriate on ConMed eCRF page, otherwise clarify. ' answered with 'Subject took these medications for dental pain, not a temperature or solicited event' (Site from DM).	Meghan York (b) (4) (b) (4)	09 Dec 2020 22:05:59
User opened query 'Per CDM RQ: Query response on Diary Dose 1(1), Temperature Log Line 7 noted. Per the participant response, medication was taken to treat pain or fever. Please reconcile and update to record the medication given as appropriate on ConMed eCRF page, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:12:42

US3142139

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 15:26:33**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:36:52

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:39:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:39:42
Data point term sent to Coder	System	11 Sep 2020 16:39:02
User entered 'bupropion'	Meghan York (b) (4)	11 Sep 2020 16:38:30
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'depression'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '300'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	11 Sep 2020 16:38:30
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:26:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'un UNK 2008'	Meghan York (b) (4)	11 Sep 2020 16:38:30
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:38:30

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:38:30

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DESVENLAFAXINE SUCCINATE, PRODUCTSYNONYM: PRISTIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:41:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:41:34
Data point term sent to Coder	System	11 Sep 2020 16:41:06
User entered 'pristiq'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'depression'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '50'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once daily (QD)'	Meghan York (b) (4)	11 Sep 2020 16:40:10
	(b) (4)	

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'UN UNK 2012'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:40:10

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:40:10



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:42:36
Data point term sent to Coder	System	11 Sep 2020 16:42:09
User entered 'ambien'	Meghan York (b) (4)	11 Sep 2020 16:41:16
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'insomnia'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '10'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'un UNK 2014'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:41:16



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:41:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:41:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:45:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 16:45:43
Data point term sent to Coder	System	11 Sep 2020 16:44:15
User entered 'lithium'	Meghan York (b) (4)	11 Sep 2020 16:43:17
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'depression'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '150'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'un UNK 2012'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:43:17

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:43:17

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:02:43
Data point term sent to Coder	System	11 Sep 2020 16:45:24
User entered 'symvastatin'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'hyper-cholesterol'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '20'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'UN UNK 2012'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:45:07

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 16:45:07

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:37:38
Data point term sent to Coder	System	01 Feb 2021 17:39:03
Coding entries removed.	Meghan York (b) (4)	01 Feb 2021 17:38:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:46:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 00:46:09
Data point term sent to Coder	System	21 Jan 2021 18:47:13
DataPoint Un-verified.	Meghan York (b) (4)	21 Jan 2021 18:46:39
Coding entries removed.	Meghan York (b) (4)	21 Jan 2021 18:46:39
User entered 'Hydrocodone acetaminophen' reason for change: Data Entry Error	Meghan York (b) (4)	21 Jan 2021 18:46:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:28:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:28:01
Data point term sent to Coder	System	17 Nov 2020 20:05:39
User entered 'Hydrocodone'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:05:16



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:10
User closed query 'Per DM CLR: Please update CM indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).		08 Feb 2021 19:57:38
Query 'Per DM CLR: Please update CM indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' answered with 'corrected ' (Site from DM).	Meghan York (b) (4)	01 Feb 2021 17:39:09
DataPoint Un-verified.	Meghan York (b) (4)	01 Feb 2021 17:38:46
User entered 'DENTAL Pain after dental surgery' reason for change: Data Entry Error	Meghan York (b) (4)	01 Feb 2021 17:38:46
User opened query 'Per DM CLR: Please update CM indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'dental surgery'	Meghan York (b) (4)	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Per DM CLR: Please note medication recorded is a single dose drug. Review as two doses are recorded. Review and update dose and dose unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:26:03
Query 'Per DM CLR: Please note medication recorded is a single dose drug. Review as two doses are recorded. Review and update dose and dose unit as appropriate.' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	21 Jan 2021 18:46:47
User opened query 'Per DM CLR: Please note medication recorded is a single dose drug. Review as two doses are recorded. Review and update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 17:27:07
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '5/325'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Other (OTHER)'	Meghan York (b) (4)	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:25:10
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		08 Feb 2021 19:58:03
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:40:34
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:40:18
User entered 'MG/MG' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:40:18
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:20:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg/act'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once (ONCE)'	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4)	17 Nov 2020 20:05:16



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '11 Aug 2020'	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '11 Aug 2020'	Meghan York (b) (4)	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	17 Nov 2020 20:06:26
User entered 'Yes (Y)'	Meghan York (b) (4)	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User entered empty.	System	17 Nov 2020 20:05:16

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User entered empty.	System	17 Nov 2020 20:05:16



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:09
User entered empty.	System	17 Nov 2020 20:05:16

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:07:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:07:50
Data point term sent to Coder	System	17 Nov 2020 20:06:40
User entered 'Tylenol'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4)	17 Nov 2020 20:06:03

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:58:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE now updated ' (Site from DM).	Meghan York (b) (4) (b) (4)	28 Jan 2021 17:40:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 17:28:23
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'pain after dental surgery'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:06:03

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:01:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'this is the dosage as indicated by the subject ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:41:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:20:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '300'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:06:03

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'mg (mg)'	Meghan York (b) (4)	17 Nov 2020 20:06:03

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'once (ONCE)'	Meghan York (b) (4)	17 Nov 2020 20:06:03



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '11 Aug 2020'	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '11 Aug 2020'	Meghan York (b) (4)	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4)	17 Nov 2020 20:06:03



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User entered empty.	System	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User entered empty.	System	17 Nov 2020 20:06:03

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:19
User entered empty.	System	17 Nov 2020 20:06:03

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 00:35:56
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 Dec 2020 00:35:56
Data point term sent to Coder	System	01 Dec 2020 19:54:06
User entered 'HYDROCODONE'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'pain after dental surgery'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'unknown'	Meghan York (b) (4)	01 Dec 2020 19:54:00
	(b) (4)	

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Other (OTHER)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'unknown'	Meghan York (b) (4)	01 Dec 2020 19:54:00
	(b) (4)	

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'unknown (UNKNOWN)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '11 Aug 2020'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '0'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered empty.	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:54:00

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:54:00

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 09:25:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 09:25:43
Data point term sent to Coder	System	14 Apr 2021 18:46:30
User entered 'OXYCOTIN'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'PAIN'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Other (OTHER)'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	14 Apr 2021 18:47:50
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:47:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:47:02
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Apr 2021 18:47:02
User entered 'as needed (PRN)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	14 Apr 2021 18:47:02
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:46:40
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Apr 2021 18:46:40
User entered empty; reason for change Data Entry Error	Lisa Jackson (b) (4) (b) (4)	14 Apr 2021 18:46:40
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Apr 2021 18:46:18
User entered 'unknown (UNKNOWN)'	Lisa Jackson (b) (4) (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty; reason for change Data Entry Error	Lisa Jackson (b) (4)	14 Apr 2021 18:47:50
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Oral (ORAL)'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '08 Oct 2020'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '0'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	Lisa Jackson (b) (4)	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:46:18

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:46:18

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 18:51:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 18:51:59
Data point term sent to Coder	System	14 Apr 2021 18:50:40
User entered 'VITAMIN D'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'GENERAL HEALTH'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:51:01
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lisa Jackson (b) (4)	14 Apr 2021 18:51:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Apr 2021 18:50:23
	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23
	(b) (4)	

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	14 Apr 2021 18:51:46
User entered 'UNKNOWN' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	14 Apr 2021 18:51:46
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	14 Apr 2021 18:51:01
User entered empty.	Lisa Jackson (b) (4) (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'as needed (PRN)'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Oral (ORAL)'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23



US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	14 Apr 2021 18:51:46
User entered '08 Oct 2020' reason for change: Data Entry Error	Lisa Jackson (b) (4)	14 Apr 2021 18:51:46
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	14 Apr 2021 18:50:23
User entered empty.	System	14 Apr 2021 18:50:23
	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '0'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	Lisa Jackson (b) (4)	14 Apr 2021 18:50:23

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:50:23

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:50:23



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:50:23

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE, PRODUCTSYNONYM: OSTEO-BI-FLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 13:46:58
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 13:46:58
Data point term sent to Coder	System	14 Apr 2021 18:56:45
User entered 'OSEOBIFLEX'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50
	(b) (4)	

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'BONE HEALTH'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Other (OTHER)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'UNKNOWN'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'unknown (UNKNOWN)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Oral (ORAL)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '08 Oct 2020'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '0'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:26:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	Lisa Jackson (b) (4)	14 Apr 2021 18:55:50



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:55:50

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:55:50

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:55:50

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 23:52:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 23:52:10
Data point term sent to Coder	System	14 Apr 2021 23:50:53
User entered 'tylenol'	Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'pain'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '500'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'mg (mg)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:26:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'three times daily (TID)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Oral (ORAL)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '09 Mar 2021'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '0'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '10 Mar 2021'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
User entered '3'	System	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
User entered '1'	System	14 Apr 2021 23:50:02

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:57
User entered '804 (804)'	System	14 Apr 2021 23:50:02

US3142139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:26:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 10:55:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 10:55:48
Data point term sent to Coder	System	14 Apr 2021 23:51:53
User entered 'hydrocodone/acetaminophen'	Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'pain'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '5/325'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'mg (mg)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'as needed (PRN)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Oral (ORAL)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '08 Mar 2021'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46



**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '0'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.		20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '09 Mar 2021'	Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:37:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'Yes (Y)'	Jill York (b) (4)	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
User entered empty.	System	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
User entered empty.	System	14 Apr 2021 23:51:46

**US3142139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:26:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:37:02
User entered empty.	System	14 Apr 2021 23:51:46

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:26:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:49:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
User closed query 'Per ETRTR: According to SAE page "Hospitalization duet o Kidney Stone", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:38:18
DataPoint Verified.		19 Apr 2021 22:37:11
Query 'Per ETRTR: According to SAE page "Hospitalization duet o Kidney Stone", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'unknown at this time. Will update as we receive records' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:52:59
User opened query 'Per ETRTR: According to SAE page "Hospitalization duet o Kidney Stone", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:25:26
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 20:06:50



US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:26:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:34
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:48:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 15:47:06
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 15:47:06
User entered '1 Sep 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:47:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:20:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Apr 2021 23:57:18
User entered 'un Sep 2020' (non-conformant).	Jill York (b) (4)	14 Apr 2021 23:57:18

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:34
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'fractured right wrist surgical repair'	Jill York (b) (4)	14 Apr 2021 23:57:18

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:34
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'Adverse Event (AE)'	Jill York (b) (4)	14 Apr 2021 23:57:18

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:26:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:34
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:57:18

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered '05 Apr 2021'	Jill York (b) (4)	14 Apr 2021 23:59:40

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:26:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'right kidney stone removal'	Jill York (b) (4)	14 Apr 2021 23:59:40

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'Adverse Event (AE)'	Jill York (b) (4)	14 Apr 2021 23:59:40

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:26:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered empty.	Jill York (b) (4)	14 Apr 2021 23:59:40



US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered '05 Apr 2021'	Jill York (b) (4)	15 Apr 2021 00:00:28

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'right kidney stent placement related to kidney stone'	Jill York (b) (4)	15 Apr 2021 00:00:28

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered 'Adverse Event (AE)'	Jill York (b) (4)	15 Apr 2021 00:00:28

US3142139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:26:33

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:20:58
User entered empty.	Jill York (b) (4)	15 Apr 2021 00:00:28

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:26:33**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:48:53
User entered '15 Apr 2021'	Jill York (b) (4)	21 Apr 2021 15:51:58

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:48:53
User entered 'REMOVAL OF RIGHT KIDNEY STONE RELATED TO KIDNEY STONE'	Jill York (b) (4)	21 Apr 2021 15:51:58

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:26:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:48:53
User entered 'Adverse Event (AE)'	Jill York (b) (4)	21 Apr 2021 15:51:58

**US3142139**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:26:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:48:53
User entered empty.	Jill York (b) (4)	21 Apr 2021 15:51:58



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User opened query 'There are no source documents for this SAE located in the subject's file' (Site from CRA).		19 Apr 2021 21:32:37
User opened query 'There are no source documents related to this SAE located in the source documents.' (Site from CRA).		19 Apr 2021 20:59:35
User closed query 'Please provide source documents for this SAE' (Site from CRA).		19 Apr 2021 20:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Query 'Please provide source documents for this SAE' answered with 'filed' (Site from CRA).	(b) (4)	
	Jill York (b) (4)	14 Apr 2021 23:53:18
User opened query 'Please provide source documents for this SAE' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:20:18
Reviewed for Safety.		07 Apr 2021 21:50:55
User entered 'USA-US064-2021-MRNA-1273-P301000010'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Ripley'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Hollister'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '4190 East Woodmen Road Suite 210'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Colorado Springs'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '80920'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'US'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 15:28:20
User entered '2'	System	07 Apr 2021 21:51:07
User entered '1'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User opened query 'There are no source documents for this SAE located in the subject's file' (Site from CRA).		19 Apr 2021 21:32:37
User opened query 'There are no source documents related to this SAE located in the source documents.' (Site from CRA).		19 Apr 2021 20:59:35
User closed query 'Please provide source documents for this SAE' (Site from CRA).		19 Apr 2021 20:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Query 'Please provide source documents for this SAE' answered with 'filed' (Site from CRA).	(b) (4)	
User opened query 'Please provide source documents for this SAE' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:53:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:20:18
User entered 'USA-US064-2021-MRNA-1273-P301000010'		07 Apr 2021 21:50:55
	System	07 Apr 2021 21:48:32



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Ripley'	System	07 Apr 2021 21:48:32



US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Hollister'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '4190 East Woodmen Road Suite 210'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Colorado Springs'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '80920'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'US'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 15:28:20
User entered '2'	System	07 Apr 2021 21:51:07
User entered '1'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:26:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '07/Apr/2021 17:50'	(b) (4) System	07 Apr 2021 21:50:48

US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:26:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'I'		07 Apr 2021 21:50:48



US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:26:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User opened query 'There are no source documents for this SAE located in the subject's file' (Site from CRA).		19 Apr 2021 21:32:37
User opened query 'There are no source documents related to this SAE located in the source documents.' (Site from CRA).		19 Apr 2021 20:59:35
User closed query 'Please provide source documents for this SAE' (Site from CRA).		19 Apr 2021 20:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Query 'Please provide source documents for this SAE' answered with 'filed' (Site from CRA).	(b) (4)	
User opened query 'Please provide source documents for this SAE' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:53:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:20:18
User entered 'USA-US064-2021-MRNA-1273-P301000010'		07 Apr 2021 21:50:55
	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Ripley'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Hollister'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '4190 East Woodmen Road Suite 210'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Colorado Springs'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '80920'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'US'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 15:28:20
User entered '2'	System	07 Apr 2021 21:51:07
User entered '1'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:26:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered '07/Apr/2021 17:51'	(b) (4) System	07 Apr 2021 21:51:07



US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:26:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 21:51:07

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User opened query 'There are no source documents for this SAE located in the subject's file' (Site from CRA).		19 Apr 2021 21:32:37
User opened query 'There are no source documents related to this SAE located in the source documents.' (Site from CRA).		19 Apr 2021 20:59:35
User closed query 'Please provide source documents for this SAE' (Site from CRA).		19 Apr 2021 20:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Query 'Please provide source documents for this SAE' answered with 'filed' (Site from CRA).	(b) (4)	
User opened query 'Please provide source documents for this SAE' (Site from CRA).	Jill York (b) (4)	14 Apr 2021 23:53:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:20:18
User entered 'USA-US064-2021-MRNA-1273-P301000010'		07 Apr 2021 21:50:55
	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Yes (Y)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'No (N)'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Ripley'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Hollister'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '4190 East Woodmen Road Suite 210'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'Colorado Springs'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered '80920'	System	07 Apr 2021 21:48:32

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:16:16
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 21:50:55
User entered 'US'	System	07 Apr 2021 21:50:48

**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:26:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 15:28:20
User entered '2'	System	07 Apr 2021 21:51:07
User entered '1'	System	07 Apr 2021 21:50:48



**US3142139**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:26:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User entered '19/Apr/2021 11:28'	System	19 Apr 2021 15:28:20

US3142139

Folder: SAE USA-US064-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:26:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:49:42
User entered 'I'		19 Apr 2021 15:28:20