

US3142236 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:29:11

All time stamps listed in this document are displayed in GMT

US3142236

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

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[Participant ID](#)

US3142236

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

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US3142236

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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

US3142236

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Date of Birth (MMM yyyy)	(b) (6)	1978
Age		41
Age Units		YEARS
Age (Derived)		41
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 21:37:04

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 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 21:37:04

Generated On: 09 Jun 2021 15:29:11

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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 21:37:04

Generated On: 09 Jun 2021 15:29:11

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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 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	NEARSIGHTED, BILATERAL
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 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	ASTIGMATISM, BILATERAL
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 (3)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	NOSE BLEEDS
Start date (dd MMM yyyy)	UN MAR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2018
Start Year (derived)	2018
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 21:37:04

Generated On: 09 Jun 2021 15:29:11

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	KIDNEY STONES
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 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
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 21:37:04

Generated On: 09 Jun 2021 15:29:11

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	SIMPLEX HERPES ON LIP
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 (10)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Condition	ACNE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3142236

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	12:05 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 12:05
Height ( <i>xxx.x</i> )	67.5 in
Weight ( <i>xxx.x</i> )	256.8 lb
BMI ( <i>xxx.x</i> )	39.70977 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 21:37:04

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Apr 2021 21:37:04

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Date of assessment (dd MMM yyyy) 19 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) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3142236

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:04

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

**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 21:37:04

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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

What was the participant's randomization number? 105632

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 21:37:05

Generated On: 09 Jun 2021 15:29:11

Height	ND - Not Done
Weight	ND - Not Done

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 12:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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: Pregnancy Test

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 12:50

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	12:26 (24 HR)
Collection date and time (derived)	19 AUG 2020 12:26



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:26	19 AUG 2020 12:26
Nasopharyngeal Swab 2	Yes	12:26	19 AUG 2020 12:26

US3142236

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 13:24

PC Open Date & Time

19 AUG 2020 13:10

PC Close Date & Time

19 AUG 2020 15:40

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	20 AUG 2020 07:16
PC Open Date & Time	19 AUG 2020 16:35
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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

21 AUG 2020 09:23

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

22 AUG 2020 08:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 11:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

24 AUG 2020 06:30

---

PC Open Date & Time

23 AUG 2020 12:00

---

PC Close Date & Time

24 AUG 2020 11:59

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US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**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

98.4 °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

25 AUG 2020 06:25

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**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

98.2 °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

26 AUG 2020 06:15

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 13:24

PC Open Date & Time

19 AUG 2020 13:10

PC Close Date & Time

19 AUG 2020 15:40

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 07:16

PC Open Date & Time

19 AUG 2020 16:35

PC Close Date & Time

20 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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

21 AUG 2020 09:24

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**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

22 AUG 2020 08:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**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

23 AUG 2020 11:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**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

24 AUG 2020 06:30

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**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

25 AUG 2020 06:26

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**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

26 AUG 2020 06:15

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 13:24
PC Open Date & Time	19 AUG 2020 13:10
PC Close Date & Time	19 AUG 2020 15:40

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 07:17
PC Open Date & Time	19 AUG 2020 16:35
PC Close Date & Time	20 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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 ☒

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 09:24
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 08:10
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 11:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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

60 of 2565

EAB) (1725)

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 06:30
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2565

EAB) (1725)

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 06:26
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**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 ☒

PRODUCTION RELEASE (v12.003

64 of 2565

EAB) (1725)

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 06:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3142236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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*

US3142236

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3142236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:58
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 16:05
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 15:31 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 15:31

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

US3142236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

15:08 (24 HR)

Collection date and time (derived)

16 SEP 2020 15:08

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	16 SEP 2020 15:03
Nasopharyngeal Swab 2	Yes	15:03	16 SEP 2020 15:03



US3142236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 16:04

PC Open Date & Time

16 SEP 2020 15:51

PC Close Date & Time

16 SEP 2020 18:21

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 17 SEP 2020 07:41

PC Open Date & Time 16 SEP 2020 19:16

PC Close Date & Time 17 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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

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

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**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

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

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

20 SEP 2020 07:11

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**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

98.1 °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

21 SEP 2020 08:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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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 ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 22 SEP 2020 06:00

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PC Open Date & Time 21 SEP 2020 12:00

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PC Close Date & Time 22 SEP 2020 11:59

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US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 23 SEP 2020 06:17

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**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

16 SEP 2020 16:05

PC Open Date & Time

16 SEP 2020 15:51

PC Close Date & Time

16 SEP 2020 18:21

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 07:41

PC Open Date & Time

16 SEP 2020 19:16

PC Close Date & Time

17 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 07:11

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 08:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 06:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 06:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 16:05
PC Open Date & Time	16 SEP 2020 15:51
PC Close Date & Time	16 SEP 2020 18:21

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 07:41
PC Open Date & Time	16 SEP 2020 19:16
PC Close Date & Time	17 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**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 ☐

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**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 15:29:11

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 08:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 ☒

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 06:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**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 ☒



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 06:18
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3142236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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*

US3142236

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:01
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	94 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
Height (derived)	
Weight (derived)	

US3142236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3142236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:10 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:10

US3142236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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

26 OCT 2020 09:46:50

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☒

Yes ☐

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

03 NOV 2020 18:19:37

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59



US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 07:04:09
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 17:51:49

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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="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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2020 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 117

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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



US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 JAN 2021 19:53:28
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 JAN 2021 11:14:33
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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



US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 187

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2021 00:01
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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 215

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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 <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"/>

**US3142236**

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

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**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 236

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 APR 2021 00:01
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US3142236

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 10:45:02

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 09:10:49

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 08:27:21

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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°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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐ Yes ☐

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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 <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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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="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"/>



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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="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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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="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"/>



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2022 23:59

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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"/>

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	07 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59
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US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**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 ☐

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2022 23:59

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US3142236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:29:11

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	Yes	16 APR 2021 10:45:59

US3142236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3142236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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) \_\_\_\_\_



US3142236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

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.*

US3142236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

16:04 (24 HR)

Collection date and time (derived)

25 MAR 2021 16:04

US3142236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

INITIAL CONTACT WAS MADE  
ON THE 12APR2021. FOLLOW UP  
WAS DONE 16APR2021

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3142236**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

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*

**US3142236**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Date of Contact 14 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☒

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐



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Form: Symptom Log (4)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 02:44:51

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐



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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 2565

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3142236

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142236

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3142236

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3142236

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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

Visit date (dd MMM yyyy)	12 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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US3142236

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Date of updated informed consent ( <i>dd MMM yyyy</i> )	12 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> )	12 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

US3142236

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Height	79 in
Weight	255.8 lb
BMI (xxx.x)	28.87728

US3142236

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Height	79 in
Weight	255.8 lb
BMI (xxx.x)	28.87728
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:56
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Height	79 in
Weight	255.8 lb
BMI (xxx.x)	28.87728
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)	12 JAN 2021
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:11
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3142236

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3142236

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

Form: Pregnancy Test

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 12 JAN 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3142236

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 15:29 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 15:29

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

US3142236

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

12 JAN 2021 15:00

US3142236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	15:00
Collection Date and Time (derived)	12 JAN 2021 15:00

US3142236

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

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



US3142236

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 15:57
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)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

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)	18 FEB 2021
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 16:40
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3142236

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3142236

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 18 FEB 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3142236

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

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) 18 FEB 2021

What was the treatment time? (00:00-23:59) 16:19 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 16:19

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

US3142236

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3142236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142236

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	16:05 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 16:05
Temperature ( <i>xxx.x</i> )	99.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142236

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

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.*

US3142236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:03

Generated On: 09 Jun 2021 15:29:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	16:04 (24 HR)
Collection date and time (derived)	25 MAR 2021 16:04

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Visit Date	20 JAN 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	16:09 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 16:09
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	90 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:05

Generated On: 09 Jun 2021 15:29:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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



US3142236

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

AEID	USA-US064-2021-MRNA-1273-P30 1000003
Adverse event	LEFT ARM PARESTHESIA
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)	20 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	21 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

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

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:44:51

Generated On: 09 Jun 2021 15:29:11

---

PATIENT EXPERIENCE  
SWELLING, REDNESS AND  
TENDERNESS AT THE  
INJECTION SITE. PATIENT  
CAME IN FOR AN  
UNSCHEDULED VISIT  
20JAN2021 AND WAS ASSESSED  
BY SUB INVESTIGATOR. THE  
PATIENT AND DOCTOR  
DISCUSSED POSSIBLE  
STERIODS OR ANTIBIOTICS IF  
SYMPTOMS WORSENER, BUT  
PATIENT DECLINED STARTING  
TREATMENT 20JAN2021.  
PATIENT WENT TO THE  
EMERGENCY ROOM ON  
21JAN2021 DUE TO LEFT SIDE  
PAIN AND PARESTHESIA.

---

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

---

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

---

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

Yes ☒

No ☐

---

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

---

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication ZYZAL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

	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 2000	
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"/>

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ONCE EVERY 10 WEEKS

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

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US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication SPIRANOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication ACNE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

	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 2015	
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 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication ADCLERAL C

Prophylaxis Yes ☐  
No ☒

Indication OBSESSIVE COMPULSIVE  
DISORDER

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
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 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication CYTOMEL

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 5

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

If dose unit is Other, specify MCG

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 21:43:58

Generated On: 09 Jun 2021 15:29:11

	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 2002	
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 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

	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 1996
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication VITAMIN B12

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify MCG

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 2 TIMES MONTHLY

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 21:43:58

Generated On: 09 Jun 2021 15:29:11

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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) _____		
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 (8)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

Name of Medication DEPO PROVERA

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

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 EVERY 3 MONTHS

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

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US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
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"/>

US3142236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 21:43:58

Generated On: 09 Jun 2021 15:29:11

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3142236

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:29:11

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

US3142236

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:29:11

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 ☐



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	22/JAN/2021 12:56
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

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	29/JAN/2021 15:11
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

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	09/MAR/2021 11:19
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.	False

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	10/MAR/2021 09:18
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

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Apr 2021 21:37:04

Generated On: 09 Jun 2021 15:29:11

SAEID	USA-US064-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	02/APR/2021 08:18
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

US3142236 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

**US3142236**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:29:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'US3142236'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:09:35



US3142236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:06:56

US3142236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:09:36

US3142236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	19 Aug 2020 19:06:56

**US3142236**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'SCRN'	System	19 Aug 2020 19:06:56

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '(b) (6)1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:09:37

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '41'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

**US3142236**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'YEARS'	System	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '41'	System	19 Aug 2020 18:57:37



US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per GCL Lab Reconciliation: Per GCL, the subject's Sex is Male, however, Female is recorded in EDC. Please confirm the subject's Sex in the query response box and reconcile the PPD portal, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 07:29:42
Query 'Per GCL Lab Reconciliation: Per GCL, the subject's Sex is Male, however, Female is recorded in EDC. Please confirm the subject's Sex in the query response box and reconcile the PPD portal, as appropriate.' answered with 'confirming subject is indeed female' (Site from DM).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:24:29
User opened query 'Per GCL Lab Reconciliation: Per GCL, the subject's Sex is Male, however, Female is recorded in EDC. Please confirm the subject's Sex in the query response box and reconcile the PPD portal, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:39:52
User entered 'Female (F)' reason for change: New Information	Jill York (b) (4)	05 Feb 2021 18:34:26
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct data and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:14:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct data and update if confirmed. Else clarify, thank you.' answered with 'Information in EDC is correct. Will review and reconcile in the Central Lab' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 18:02:37

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

Sex

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1, Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct data and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:29:28
User entered 'Male (M)'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

**US3142236**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:11**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32



US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

**US3142236**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:11**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

**US3142236**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:11**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:32

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:37

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Aug 2020'	System	19 Aug 2020 18:57:37

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2020'	System	19 Aug 2020 18:57:37

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Meghan York (b) (4)	09 Dec 2020 23:43:42
User entered 'Amendment 1 (1)'	(b) (4)	
	Meghan York (b) (4)	19 Aug 2020 18:57:37
	(b) (4)	



US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:37

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:37

**US3142236**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:11**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:37

**US3142236**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:11**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:37

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:09:36

US3142236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'I'	System	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:29:11

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:29:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:07:39



US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per DM CLR: Please specify the eye laterality that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 06:33:03
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:06:23
Data point term sent to Coder	System	19 Oct 2020 20:05:22
Query 'Per DM CLR: Please specify the eye laterality that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:04:59
Coding entries removed.	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:04:55
User entered 'NEARSIGHTED, bilateral' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:04:55
User opened query 'Per DM CLR: Please specify the eye laterality that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 07:38:35
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:20
Data point term sent to Coder	System	19 Aug 2020 19:08:39
User entered 'nearsighted'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:08:08

US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 2010'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:08

**US3142236**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:08

US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:08

**US3142236**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:08

US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:08

US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 2010'	System	19 Aug 2020 19:08:08

**US3142236**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2010'	System	19 Aug 2020 19:08:08



US3142236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:08:08

**US3142236**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:08:08

US3142236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per DM CLR: Please specify the laterality of eye with ASTIGMATISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 06:33:14
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:06:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:06:22
Data point term sent to Coder	System	19 Oct 2020 20:05:23
Query 'Per DM CLR: Please specify the laterality of eye with ASTIGMATISM. Review and update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:05:15
Coding entries removed.	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:05:10
User entered 'ASTIGMATISM, bilateral' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	19 Oct 2020 20:05:10
User opened query 'Per DM CLR: Please specify the laterality of eye with ASTIGMATISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 07:38:54
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:22
Data point term sent to Coder	System	19 Aug 2020 19:08:39
User entered 'astigmatism'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:08:24

**US3142236**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 2010'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:24

**US3142236**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:24

US3142236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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	19 Aug 2020 19:08:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4)	19 Aug 2020 19:08:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Aug 2020 19:08:24
	Meghan York (b) (4)	19 Aug 2020 19:08:24
	(b) (4)	

**US3142236**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:24

US3142236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:08:24



US3142236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 2010'	System	19 Aug 2020 19:08:24

US3142236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2010'	System	19 Aug 2020 19:08:24

**US3142236**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:08:24

**US3142236**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:08:24

US3142236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nose bleeds - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:10:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:10:26
Data point term sent to Coder	System	19 Aug 2020 19:09:43
User entered 'nose bleeds'	Meghan York (b) (4)	19 Aug 2020 19:09:24

**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN Mar 2018'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:24

**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:24

US3142236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:24



**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:24

**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:24

US3142236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Mar 2018'	System	19 Aug 2020 19:09:24

**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2018'	System	19 Aug 2020 19:09:24

US3142236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:09:24

**US3142236**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:09:24

US3142236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:11:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:11:27
Data point term sent to Coder	System	19 Aug 2020 19:10:44
User entered 'seasonal allergies'	Meghan York (b) (4)	19 Aug 2020 19:09:51

**US3142236**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 2000'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:51



**US3142236**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:51

US3142236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:51

US3142236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:51

**US3142236**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:09:51

US3142236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 2000'	System	19 Aug 2020 19:09:51

US3142236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2000'	System	19 Aug 2020 19:09:51

**US3142236**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:09:51

**US3142236**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:09:51



US3142236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:11:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:11:36
Data point term sent to Coder	System	19 Aug 2020 19:10:44
User entered 'kidney stones'	Meghan York (b) (4)	19 Aug 2020 19:10:31

US3142236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN Mar 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:10:31

**US3142236**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:10:31

US3142236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:10:31

US3142236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN Mar 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:10:31

**US3142236**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:10:31

US3142236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Mar 2020'	System	19 Aug 2020 19:10:31

**US3142236**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2020'	System	19 Aug 2020 19:10:31



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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Mar 2020'	System	19 Aug 2020 19:10:31

**US3142236**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2020'	System	19 Aug 2020 19:10:31

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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 for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:46:47
Query 'Per DM CLR: Please note that there is no Con Meghan York 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 for no medical treatment.' answered with 'ConMed page is now complete ' (Site from DM).	(b) (4)	23 Oct 2020 16:11:46
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 for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 07:39:23
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)	19 Aug 2020 19:12:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:12:31
Data point term sent to Coder	System	19 Aug 2020 19:11:48
User entered 'hypothyroidism'	Meghan York (b) (4)	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 1996'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:05

**US3142236**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:05

**US3142236**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:05



US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 1996'	System	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '1996'	System	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:05

**US3142236**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:05

US3142236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:12:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:12:32
Data point term sent to Coder	System	19 Aug 2020 19:11:51
User entered 'migraines'	Meghan York (b) (4)	19 Aug 2020 19:11:32

US3142236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 2015'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:32

US3142236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:32

US3142236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:32



**US3142236**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:32

**US3142236**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:32

**US3142236**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 2015'	System	19 Aug 2020 19:11:32

US3142236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2015'	System	19 Aug 2020 19:11:32

**US3142236**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:32

**US3142236**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:32

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Obsessive-compulsive disorders and symptoms, PT: Obsessive-compulsive disorder, LLT: Obsessive-compulsive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:15:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:15:25
Data point term sent to Coder	System	19 Aug 2020 19:12:51
User entered 'ocd'	Meghan York (b) (4)	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 2005'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:56



**US3142236**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:56

**US3142236**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 2005'	System	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '2005'	System	19 Aug 2020 19:11:56

**US3142236**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:56

US3142236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:11:56



US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per DM CLR: Please specify the location and/or type of SIMPLEX HERPES. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:54:24
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Herpes simplex labialis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:14:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:14:34
Data point term sent to Coder	System	23 Oct 2020 16:13:17
Query 'Per DM CLR: Please specify the location and/or type of SIMPLEX HERPES. Review and update Med History eCRF as appropriate. ' answered with 'done ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:12:30
Coding entries removed.	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:12:23
User entered 'SIMPLEX HERPES on lip' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:12:23
User opened query 'Per DM CLR: Please specify the location and/or type of SIMPLEX HERPES. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 07:39:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:15:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:15:26
Data point term sent to Coder	System	19 Aug 2020 19:12:52
User entered 'simplex herpes'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:12:17

US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'UN UNK 1980'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:12:17

**US3142236**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:12:17

US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:12:17

US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:12:17

**US3142236**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:12:17

**US3142236**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'Jan 1980'	System	19 Aug 2020 19:12:17

**US3142236**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '1980'	System	19 Aug 2020 19:12:17



US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:12:17

US3142236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	19 Aug 2020 19:12:17

US3142236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:34:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:34:50
Data point term sent to Coder	System	25 Jan 2021 18:33:47
User entered 'acne'	Meghan York (b) (4)	25 Jan 2021 18:33:29

US3142236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:33:29

**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4) Meghan York (b) (4) (b) (4)	25 Jan 2021 18:33:29

US3142236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:33:29

**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:33:29

**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:33:29



**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	25 Jan 2021 18:33:29

**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	25 Jan 2021 18:33:29

US3142236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	25 Jan 2021 18:33:29

**US3142236**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:29:11**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	25 Jan 2021 18:33:29

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:05'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '19 Aug 2020 12:05'	System	19 Aug 2020 19:13:26



US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '67.5' in	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:26
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '256.8' lb	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:26
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
Amendment Manager: User entered '39.70977'	System	17 Sep 2020 00:14:35
User entered '39.7'	System	19 Aug 2020 19:13:26
DataPoint set to visible.	System	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'kg/m2'	System	19 Aug 2020 19:13:26
DataPoint set to visible.	System	19 Aug 2020 18:57:43

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:30:31
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	29 Sep 2020 15:15:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 17:56:18
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	30 Aug 2020 08:22:03
User entered '98.5' F	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	21 Sep 2020 17:56:18
User entered 'Other (Other)'	(b) (4)	
	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	21 Sep 2020 17:56:18
User entered 'temporal'	(b) (4)	
	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:56:18
User entered '92'	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	



US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'bpm'	System	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:56:18
User entered '14'	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'breaths/min'	System	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:56:18
User entered '128'	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:56:18
User entered '98'	Meghan York (b) (4)	19 Aug 2020 19:13:26
	(b) (4)	

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	19 Aug 2020 19:13:26

US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15



US3142236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15

US3142236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:13:34

US3142236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '19 Aug 2020' reason for change: Data Entry Error	System	19 Aug 2020 19:13:40
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	Meghan York (b) (4)	19 Aug 2020 19:13:40
User entered empty.	(b) (4)	
	System	19 Aug 2020 19:13:34
	Meghan York (b) (4)	19 Aug 2020 19:13:34
	(b) (4)	

US3142236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

US3142236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

US3142236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

US3142236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:23



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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

US3142236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:11

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	Jami Wagner (b) (4)	01 Apr 2021 22:04:23

US3142236

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Urine (URINE)'	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Negative (NEGATIVE)'	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	Jami Wagner (b) (4)	01 Apr 2021 22:04:56



**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:04:56

**US3142236**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	01 Apr 2021 22:04:56

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:15:58



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58
	(b) (4)	

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

**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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58

US3142236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:15:58



US3142236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:16:11

US3142236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:16:11

US3142236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	19 Aug 2020 19:16:11

US3142236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'VISIT1'	System	19 Aug 2020 19:16:11

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:39:33

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:39:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:39:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 18:39:33
User entered '105632' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:39:33

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:39:33

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:16:20



US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:16:20

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	(b) (4)	19 Aug 2020 19:16:34
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	19 Aug 2020 19:16:34
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:16:20
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Aug 2020 19:16:20

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:16:20

US3142236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:16:20

**US3142236**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:11**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
DataPoint set to visible.	System	09 Dec 2020 23:43:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:57

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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 HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:30:39
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)	29 Sep 2020 15:14:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 17:55:44
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)	01 Sep 2020 07:16:02
User entered '67.5' in	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:55:44
User entered '256.8' lb	Meghan York (b) (4)	19 Aug 2020 19:45:20
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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 HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:30:39
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)	29 Sep 2020 15:14:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 17:55:44
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)	01 Sep 2020 07:16:02
User entered '67.5' in	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20



US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:55:44
User entered '256.8' lb	Meghan York (b) (4)	19 Aug 2020 19:45:20
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:05'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 12:05'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '98.5' F	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20



US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'temporal'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '73'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'bpm'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'breaths/min'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '128'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'mmHg'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '98'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20



US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'mmHg'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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 HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:30:39
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)	29 Sep 2020 15:14:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 17:55:44
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)	01 Sep 2020 07:16:02
User entered '67.5' in	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 17:55:44
User entered '256.8' lb	Meghan York (b) (4)	19 Aug 2020 19:45:20
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:39:16
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).		19 Aug 2020 19:45:20
User entered '13:20'	Meghan York (b) (4)	19 Aug 2020 19:45:20
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 13:20'	System	19 Aug 2020 19:45:20



US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '98.1' F	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'temporal'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '92'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'bpm'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'breaths/min'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '109'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20



US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'mmHg'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '87'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'mmHg'	System	19 Aug 2020 19:45:20

US3142236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Meghan York (b) (4)	29 Sep 2020 15:14:51
User entered 'Yes (Y)'	(b) (4)	
	Meghan York (b) (4)	19 Aug 2020 19:17:06
	(b) (4)	

US3142236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	29 Sep 2020 15:14:51
User entered '19 Aug 2020'	Meghan York (b) (4)	19 Aug 2020 19:17:06

US3142236

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 22:06:12

US3142236

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Apr 2021 22:06:54
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	01 Apr 2021 22:06:54
User entered '19 Aug 2020' reason for change: Data Entry Error	Jami Wagner (b) (4)	01 Apr 2021 22:06:54
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Apr 2021 22:06:12
User entered '16 Sep 2020'	System	01 Apr 2021 22:06:12
	Jami Wagner (b) (4)	01 Apr 2021 22:06:12
	(b) (4)	

**US3142236**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Urine (URINE)'	Jami Wagner (b) (4)	01 Apr 2021 22:06:12



**US3142236**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Negative (NEGATIVE)'	Jami Wagner (b) (4)	01 Apr 2021 22:06:12

US3142236

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	Jami Wagner (b) (4)	01 Apr 2021 22:06:12

**US3142236**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:06:12

**US3142236**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:06:12

**US3142236**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered empty.	System	01 Apr 2021 22:06:12

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

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)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	19 Aug 2020 18:58:24



US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:50'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 12:50'	System	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'ONCE'	System	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 18:58:24

US3142236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:24



US3142236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:24

US3142236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:26'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:24

US3142236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 19:17:24

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '19 Aug 2020'	Meghan York (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:26'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 19:17:41



US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12:26'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 19:17:41

US3142236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	19 Aug 2020 19:17:46

US3142236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:50
User entered 'I'	System	19 Aug 2020 19:17:46

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:23:52', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dc20b151-5ca2-497c-b33b-da79fecb8ed6' User entered 'Yes (Y)'	System	19 Aug 2020 19:24:14
	System	19 Aug 2020 19:24:14



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:01', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dc20b151-5ca2-497c-b33b-da79fecb8ed6' User entered '98.1'	System	19 Aug 2020 19:24:14
	System	19 Aug 2020 19:24:14

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dc20b151-5ca2-497c-b33b-da79fecb8ed6'	System	19 Aug 2020 19:24:14
User entered 'No (N)'	System	19 Aug 2020 19:24:14

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:11', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dc20b151-5ca2-497c-b33b-da79fecb8ed6'	System	19 Aug 2020 19:24:14
User entered '19 Aug 2020 13:24'	System	19 Aug 2020 19:24:14

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 13:10'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 15:40'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:13', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd256ce76-2c95-4a22-8e85-e92b6cfda471' User entered 'Yes (Y)'	System	20 Aug 2020 13:16:39
	System	20 Aug 2020 13:16:39

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:28', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd256ce76-2c95-4a22-8e85-e92b6cfda471' User entered '97.9'	System	20 Aug 2020 13:16:39
	System	20 Aug 2020 13:16:39



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:32', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd256ce76-2c95-4a22-8e85-e92b6cfda471' User entered 'No (N)'	System	20 Aug 2020 13:16:39
	System	20 Aug 2020 13:16:39

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:37', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd256ce76-2c95-4a22-8e85-e92b6cfda471' User entered '20 Aug 2020 07:16'	System	20 Aug 2020 13:16:39
	System	20 Aug 2020 13:16:39

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 16:35'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 2'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:23:36', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '227a16b7-40df-4f20-a501-fedfc0375208'	System	21 Aug 2020 15:23:55
User entered 'Yes (Y)'	System	21 Aug 2020 15:23:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:23:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '227a16b7-40df-4f20-a501-fedfc0375208' User entered '98.4'	System	21 Aug 2020 15:23:55
	System	21 Aug 2020 15:23:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:23:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '227a16b7-40df-4f20-a501-fedfc0375208'	System	21 Aug 2020 15:23:55
User entered 'No (N)'	System	21 Aug 2020 15:23:55



**US3142236**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:23:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '227a16b7-40df-4f20-a501-fedfc0375208' User entered '21 Aug 2020 09:23'	System	21 Aug 2020 15:23:55
	System	21 Aug 2020 15:23:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 3'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:09:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9445ce0a-cffb-49d7-af27-5d58780cf195'	System	22 Aug 2020 14:10:13
User entered 'Yes (Y)'	System	22 Aug 2020 14:10:13

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:05', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9445ce0a-cffb-49d7-af27-5d58780cf195' User entered '97.9'	System	22 Aug 2020 14:10:13
	System	22 Aug 2020 14:10:13

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9445ce0a-cffb-49d7-af27-5d58780cf195'	System	22 Aug 2020 14:10:13
User entered 'No (N)'	System	22 Aug 2020 14:10:13

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:11', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9445ce0a-cffb-49d7-af27-5d58780cf195'	System	22 Aug 2020 14:10:13
User entered '22 Aug 2020 08:10'	System	22 Aug 2020 14:10:13



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 4'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:31', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '7f1f5d02-7692-43b1-9b78-0687e4547315' User entered 'Yes (Y)'	System	23 Aug 2020 17:43:45
	System	23 Aug 2020 17:43:45

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '7f1f5d02-7692-43b1-9b78-0687e4547315' User entered '97.6'	System	23 Aug 2020 17:43:45
	System	23 Aug 2020 17:43:45

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:38', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '7f1f5d02-7692-43b1-9b78-0687e4547315' User entered 'No (N)'	System	23 Aug 2020 17:43:45
	System	23 Aug 2020 17:43:45

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:40', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '7f1f5d02-7692-43b1-9b78-0687e4547315' User entered '23 Aug 2020 11:43'	System	23 Aug 2020 17:43:45
	System	23 Aug 2020 17:43:45

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 5'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e90c59c2-8682-40b0-9e52-561c3c3a721f' User entered 'Yes (Y)'	System	24 Aug 2020 12:30:23
	System	24 Aug 2020 12:30:23

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:14', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e90c59c2-8682-40b0-9e52-561c3c3a721f' User entered '98.1'	System	24 Aug 2020 12:30:23
	System	24 Aug 2020 12:30:23

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:17', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e90c59c2-8682-40b0-9e52-561c3c3a721f' User entered 'No (N)'	System	24 Aug 2020 12:30:23
	System	24 Aug 2020 12:30:23

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e90c59c2-8682-40b0-9e52-561c3c3a721f' User entered '24 Aug 2020 06:30'	System	24 Aug 2020 12:30:23
	System	24 Aug 2020 12:30:23

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 6'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:25:39', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b3b27376-594a-4abf-9000-7d562cf6c43a' User entered 'Yes (Y)'	System	25 Aug 2020 12:25:55
	System	25 Aug 2020 12:25:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:25:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b3b27376-594a-4abf-9000-7d562cf6c43a' User entered '98.4'	System	25 Aug 2020 12:25:55
	System	25 Aug 2020 12:25:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:25:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b3b27376-594a-4abf-9000-7d562cf6c43a' User entered 'No (N)'	System	25 Aug 2020 12:25:55
	System	25 Aug 2020 12:25:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:25:52', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b3b27376-594a-4abf-9000-7d562cf6c43a' User entered '25 Aug 2020 06:25'	System	25 Aug 2020 12:25:55
	System	25 Aug 2020 12:25:55

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 7'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:14:52', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '494fd7ab-c5e7-4ade-ba4f-d22ef3164282' User entered 'Yes (Y)'	System	26 Aug 2020 12:15:12
	System	26 Aug 2020 12:15:12

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:03', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '494fd7ab-c5e7-4ade-ba4f-d22ef3164282' User entered '98.2'	System	26 Aug 2020 12:15:12
	System	26 Aug 2020 12:15:12

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:07', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '494fd7ab-c5e7-4ade-ba4f-d22ef3164282'	System	26 Aug 2020 12:15:12
User entered 'No (N)'	System	26 Aug 2020 12:15:12

**US3142236**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:10', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '494fd7ab-c5e7-4ade-ba4f-d22ef3164282' User entered '26 Aug 2020 06:15'	System	26 Aug 2020 12:15:12
	System	26 Aug 2020 12:15:12

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:19', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '1c8c51c8-ad6d-484f-9817-8513c792c545' User entered 'None (1)'	System	19 Aug 2020 19:24:38
	System	19 Aug 2020 19:24:38



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '1c8c51c8-ad6d-484f-9817-8513c792c545'	System	19 Aug 2020 19:24:38
User entered 'No (N)'	System	19 Aug 2020 19:24:38

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:30', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '1c8c51c8-ad6d-484f-9817-8513c792c545' User entered 'No (N)'	System	19 Aug 2020 19:24:38
	System	19 Aug 2020 19:24:38

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:32', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '1c8c51c8-ad6d-484f-9817-8513c792c545' User entered 'None (1)'	System	19 Aug 2020 19:24:38
	System	19 Aug 2020 19:24:38

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '1c8c51c8-ad6d-484f-9817-8513c792c545' User entered '19 Aug 2020 13:24'	System	19 Aug 2020 19:24:38
	System	19 Aug 2020 19:24:38

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 13:10'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 15:40'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:43', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '72042e4c-0241-48d2-a116-020ab9c3e5df' User entered 'None (1)'	System	20 Aug 2020 13:16:57
	System	20 Aug 2020 13:16:57



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '72042e4c-0241-48d2-a116-020ab9c3e5df' User entered 'No (N)'	System	20 Aug 2020 13:16:57
	System	20 Aug 2020 13:16:57

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:49', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '72042e4c-0241-48d2-a116-020ab9c3e5df' User entered 'No (N)'	System	20 Aug 2020 13:16:57
	System	20 Aug 2020 13:16:57

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:51', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '72042e4c-0241-48d2-a116-020ab9c3e5df' User entered 'None (1)'	System	20 Aug 2020 13:16:57
	System	20 Aug 2020 13:16:57

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:54', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '72042e4c-0241-48d2-a116-020ab9c3e5df' User entered '20 Aug 2020 07:16'	System	20 Aug 2020 13:16:57
	System	20 Aug 2020 13:16:57

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 16:35'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 2'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:23:57', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '92f595e8-3da5-42d1-babb-95090aecf4f0'	System	21 Aug 2020 15:24:11
User entered 'None (1)'	System	21 Aug 2020 15:24:11



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '92f595e8-3da5-42d1-babb-95090aecf4f0'	System	21 Aug 2020 15:24:11
User entered 'No (N)'	System	21 Aug 2020 15:24:11

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:03', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '92f595e8-3da5-42d1-babb-95090aecf4f0'	System	21 Aug 2020 15:24:11
User entered 'No (N)'	System	21 Aug 2020 15:24:11

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:05', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '92f595e8-3da5-42d1-babb-95090aecf4f0'	System	21 Aug 2020 15:24:11
User entered 'None (1)'	System	21 Aug 2020 15:24:11

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '92f595e8-3da5-42d1-babb-95090aecf4f0' User entered '21 Aug 2020 09:24'	System	21 Aug 2020 15:24:11
	System	21 Aug 2020 15:24:11

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 3'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '341011b2-f627-462a-84ee-ea9da306d5b0' User entered 'None (1)'	System	22 Aug 2020 14:10:24
	System	22 Aug 2020 14:10:24



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '341011b2-f627-462a-84ee-ea9da306d5b0'	System	22 Aug 2020 14:10:24
User entered 'No (N)'	System	22 Aug 2020 14:10:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:30', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '341011b2-f627-462a-84ee-ea9da306d5b0' User entered 'No (N)'	System	22 Aug 2020 14:10:24
	System	22 Aug 2020 14:10:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '341011b2-f627-462a-84ee-ea9da306d5b0' User entered 'None (1)'	System	22 Aug 2020 14:10:24
	System	22 Aug 2020 14:10:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '341011b2-f627-462a-84ee-ea9da306d5b0' User entered '22 Aug 2020 08:10'	System	22 Aug 2020 14:10:24
	System	22 Aug 2020 14:10:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 4'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:43', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '6af6d394-7d01-458a-b7f3-4a4b05daa96e' User entered 'None (1)'	System	23 Aug 2020 17:43:56
	System	23 Aug 2020 17:43:56



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:46', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '6af6d394-7d01-458a-b7f3-4a4b05daa96e' User entered 'No (N)'	System	23 Aug 2020 17:43:56
	System	23 Aug 2020 17:43:56

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '6af6d394-7d01-458a-b7f3-4a4b05daa96e' User entered 'No (N)'	System	23 Aug 2020 17:43:56
	System	23 Aug 2020 17:43:56

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:49', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '6af6d394-7d01-458a-b7f3-4a4b05daa96e' User entered 'None (1)'	System	23 Aug 2020 17:43:56
	System	23 Aug 2020 17:43:56

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:52', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '6af6d394-7d01-458a-b7f3-4a4b05daa96e' User entered '23 Aug 2020 11:43'	System	23 Aug 2020 17:43:56
	System	23 Aug 2020 17:43:56

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 5'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd84b4477-ac75-471c-9c37-a6087070b28a' User entered 'None (1)'	System	24 Aug 2020 12:30:36
	System	24 Aug 2020 12:30:36



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd84b4477-ac75-471c-9c37-a6087070b28a' User entered 'No (N)'	System	24 Aug 2020 12:30:36
	System	24 Aug 2020 12:30:36

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd84b4477-ac75-471c-9c37-a6087070b28a' User entered 'No (N)'	System	24 Aug 2020 12:30:36
	System	24 Aug 2020 12:30:36

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:31', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd84b4477-ac75-471c-9c37-a6087070b28a' User entered 'None (1)'	System	24 Aug 2020 12:30:36
	System	24 Aug 2020 12:30:36

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:34', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd84b4477-ac75-471c-9c37-a6087070b28a' User entered '24 Aug 2020 06:30'	System	24 Aug 2020 12:30:36
	System	24 Aug 2020 12:30:36

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 6'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3491a02a-2df3-433c-89be-b2fb5493250b' User entered 'None (1)'	System	25 Aug 2020 12:26:17
	System	25 Aug 2020 12:26:17



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:04', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3491a02a-2df3-433c-89be-b2fb5493250b' User entered 'No (N)'	System	25 Aug 2020 12:26:17
	System	25 Aug 2020 12:26:17

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:09', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3491a02a-2df3-433c-89be-b2fb5493250b' User entered 'No (N)'	System	25 Aug 2020 12:26:17
	System	25 Aug 2020 12:26:17

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:11', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3491a02a-2df3-433c-89be-b2fb5493250b' User entered 'None (1)'	System	25 Aug 2020 12:26:17
	System	25 Aug 2020 12:26:17

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3491a02a-2df3-433c-89be-b2fb5493250b' User entered '25 Aug 2020 06:26'	System	25 Aug 2020 12:26:17
	System	25 Aug 2020 12:26:17

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 7'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5aec31cc-cf94-4f4b-859e-b5fa1c7211e2'	System	26 Aug 2020 12:15:26
User entered 'None (1)'	System	26 Aug 2020 12:15:26



US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:17', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5aec31cc-cf94-4f4b-859e-b5fa1c7211e2'	System	26 Aug 2020 12:15:26
User entered 'No (N)'	System	26 Aug 2020 12:15:26

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:19', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5aec31cc-cf94-4f4b-859e-b5fa1c7211e2'	System	26 Aug 2020 12:15:26
User entered 'No (N)'	System	26 Aug 2020 12:15:26

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5aec31cc-cf94-4f4b-859e-b5fa1c7211e2' User entered 'None (1)'	System	26 Aug 2020 12:15:26
	System	26 Aug 2020 12:15:26

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5aec31cc-cf94-4f4b-859e-b5fa1c7211e2' User entered '26 Aug 2020 06:15'	System	26 Aug 2020 12:15:26
	System	26 Aug 2020 12:15:26

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:41', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:48', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:50', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered 'None (0)'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58'	System	19 Aug 2020 19:24:57
User entered 'No (N)'	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-19T13:24:55', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b2127f2-f199-4d16-b0ab-2cba1d285c58' User entered '19 Aug 2020 13:24'	System	19 Aug 2020 19:24:57
	System	19 Aug 2020 19:24:57

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 13:10'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 15:40'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:16:58', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:04', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:12', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered 'None (0)'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:21', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972'	System	20 Aug 2020 13:17:28
User entered 'No (N)'	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-20T07:17:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd59a4e52-3725-431e-a01c-9e54ceb9f972' User entered '20 Aug 2020 07:17'	System	20 Aug 2020 13:17:28
	System	20 Aug 2020 13:17:28

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Aug 2020 16:35'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 2'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:12', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:18', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:21', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:26', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'None (0)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:34', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered 'No (N)'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T09:24:37', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8b138e60-93b2-47f0-bb83-4477a80cda02' User entered '21 Aug 2020 09:24'	System	21 Aug 2020 15:24:41
	System	21 Aug 2020 15:24:41

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 3'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:51', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:54', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:57', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:21:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:22:01', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-21T20:22:03', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'None (0)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:26', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered 'No (N)'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31

**US3142236**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-22T08:10:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2f01c36d-d67b-4b5c-8be8-6b3c81528d1e' User entered '22 Aug 2020 08:10'	System	22 Aug 2020 14:10:31
	System	22 Aug 2020 14:10:31



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 4'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:43:58', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:01', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:04', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:19', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:23', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'None (0)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:28', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered 'No (N)'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-23T11:44:31', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '54d91e10-0c33-4149-b00a-1f7486529621' User entered '23 Aug 2020 11:44'	System	23 Aug 2020 17:44:36
	System	23 Aug 2020 17:44:36

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 5'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:37', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:39', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:41', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:42', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

**US3142236**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'None (0)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:48', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered 'No (N)'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

**US3142236**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-24T06:30:50', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'dd11f834-ab30-423a-9c1d-401f555abe85' User entered '24 Aug 2020 06:30'	System	24 Aug 2020 12:30:55
	System	24 Aug 2020 12:30:55

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:58:24



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 6'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:19', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:21', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:23', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:25', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'None (0)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:32', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered 'No (N)'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-25T06:26:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c01eaba4-aaa9-419d-b6a9-c03179c3190e' User entered '25 Aug 2020 06:26'	System	25 Aug 2020 12:26:38
	System	25 Aug 2020 12:26:38

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 7'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:27', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:30', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:32', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42



US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:33', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'None (0)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:37', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered 'No (N)'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-08-26T06:15:39', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '449e15bf-0a69-4c59-b8b6-6c84acb86c43' User entered '26 Aug 2020 06:15'	System	26 Aug 2020 12:15:42
	System	26 Aug 2020 12:15:42

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:58:24

US3142236

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 02:56:23

US3142236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '27 Aug 2020'	Jami Wagner (b) (4)	31 Aug 2020 02:56:23



US3142236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	31 Aug 2020 02:56:23

US3142236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	31 Aug 2020 02:56:23

US3142236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 02:56:28

**US3142236**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:35
User entered 'I'	System	31 Aug 2020 02:56:28

**US3142236**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Sep 2020 16:54:36

US3142236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 03:40:33
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct' (Site from System).	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 16:54:49
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 16:54:36
User entered '08 Sep 2020'	Jami Wagner (b) (4) (b) (4)	10 Sep 2020 16:54:36

US3142236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	10 Sep 2020 16:54:36

US3142236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	10 Sep 2020 16:54:36



US3142236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Sep 2020 16:54:57

US3142236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:56
User entered 'I'	System	10 Sep 2020 16:54:57

**US3142236**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	14 Sep 2020 21:33:10

US3142236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 15:06:11
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data entered is correct' (Site from System).	Jami Wagner (b) (4)	14 Sep 2020 21:33:22
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 21:33:10
User entered '14 Sep 2020'	Jami Wagner (b) (4)	14 Sep 2020 21:33:10

US3142236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	14 Sep 2020 21:33:10

US3142236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	14 Sep 2020 21:33:10

US3142236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	14 Sep 2020 21:33:35

US3142236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:26
User entered 'I'	System	14 Sep 2020 21:33:35



US3142236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:50:05

US3142236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:50:05

US3142236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:50:05

US3142236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'VISIT2'	System	21 Sep 2020 19:50:05

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14:58'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38



US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 14:58'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '98.7' F	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '86'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'bpm'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'breaths/min'	System	21 Sep 2020 19:51:38



US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '118'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '84'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:05'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38



US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 16:05'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '97.8' F	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '73'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'bpm'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'breaths/min'	System	21 Sep 2020 19:51:38



US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '128'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '89'	(b) (4) Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	21 Sep 2020 19:51:38

US3142236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:50:14

US3142236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:50:14

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	Jami Wagner (b) (4)	01 Apr 2021 22:07:23



US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Urine (URINE)'	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Negative (NEGATIVE)'	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:07:23

**US3142236**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered empty.	System	01 Apr 2021 22:07:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 22:01:36



US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

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 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:31'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'ONCE'	System	16 Sep 2020 22:01:36

US3142236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 22:01:36



US3142236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:52:58

US3142236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:52:58

US3142236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:08'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:52:58

US3142236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 15:08'	System	21 Sep 2020 19:52:58

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:03'	(b) (4) Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:53:23



US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 15:03'	System	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:03'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:53:23

**US3142236**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '16 Sep 2020 15:03'	System	21 Sep 2020 19:53:23

US3142236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Sep 2020 19:53:28

US3142236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	21 Sep 2020 19:53:28

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b6cbf515-e596-46ea-a295-fb95361eca90' User entered 'Yes (Y)'	System	16 Sep 2020 22:04:49
	System	16 Sep 2020 22:04:49

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:36', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b6cbf515-e596-46ea-a295-fb95361eca90' User entered '97.8'	System	16 Sep 2020 22:04:49
	System	16 Sep 2020 22:04:49

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:42', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b6cbf515-e596-46ea-a295-fb95361eca90'	System	16 Sep 2020 22:04:49
User entered 'No (N)'	System	16 Sep 2020 22:04:49

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'b6cbf515-e596-46ea-a295-fb95361eca90'	System	16 Sep 2020 22:04:49
User entered '16 Sep 2020 16:04'	System	16 Sep 2020 22:04:49

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 18:21'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:40:54', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'bd59dcb1-c84b-4533-8ff4-2f30e99a43ae' User entered 'No (N)'	System	17 Sep 2020 13:41:04
	System	17 Sep 2020 13:41:04



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:40:57', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'bd59dcb1-c84b-4533-8ff4-2f30e99a43ae'	System	17 Sep 2020 13:41:04
User entered 'No (N)'	System	17 Sep 2020 13:41:04

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:01', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'bd59dcb1-c84b-4533-8ff4-2f30e99a43ae'	System	17 Sep 2020 13:41:04
User entered '17 Sep 2020 07:41'	System	17 Sep 2020 13:41:04

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 19:16'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 2'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 3'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 4'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:28', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'a274a1a2-00bb-41b1-b9f4-650004ba3ebc' User entered 'Yes (Y)'	System	20 Sep 2020 13:11:46
	System	20 Sep 2020 13:11:46



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'a274a1a2-00bb-41b1-b9f4-650004ba3ebc' User entered '97.9'	System	20 Sep 2020 13:11:46
	System	20 Sep 2020 13:11:46

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:39', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'a274a1a2-00bb-41b1-b9f4-650004ba3ebc' User entered 'No (N)'	System	20 Sep 2020 13:11:46
	System	20 Sep 2020 13:11:46

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'a274a1a2-00bb-41b1-b9f4-650004ba3ebc' User entered '20 Sep 2020 07:11'	System	20 Sep 2020 13:11:46
	System	20 Sep 2020 13:11:46

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 5'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:00:43', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'ad3bf318-11e5-497d-8f24-6a51f8e88c88'	System	21 Sep 2020 14:01:02
User entered 'Yes (Y)'	System	21 Sep 2020 14:01:02

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:00:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'ad3bf318-11e5-497d-8f24-6a51f8e88c88' User entered '98.1'	System	21 Sep 2020 14:01:02
	System	21 Sep 2020 14:01:02



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:00:54', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'ad3bf318-11e5-497d-8f24-6a51f8e88c88'	System	21 Sep 2020 14:01:02
User entered 'No (N)'	System	21 Sep 2020 14:01:02

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:00:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'ad3bf318-11e5-497d-8f24-6a51f8e88c88' User entered '21 Sep 2020 08:00'	System	21 Sep 2020 14:01:02
	System	21 Sep 2020 14:01:02

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 6'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:35', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '35dfb537-3781-4a0a-bbd0-a6c390e25d97'	System	22 Sep 2020 12:00:48
User entered 'No (N)'	System	22 Sep 2020 12:00:48

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:38', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '35dfb537-3781-4a0a-bbd0-a6c390e25d97'	System	22 Sep 2020 12:00:48
User entered 'No (N)'	System	22 Sep 2020 12:00:48

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:42', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '35dfb537-3781-4a0a-bbd0-a6c390e25d97' User entered '22 Sep 2020 06:00'	System	22 Sep 2020 12:00:48
	System	22 Sep 2020 12:00:48



US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 7'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:17:43', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '83455e3f-4615-4004-95e7-6131b0daeeed' User entered 'No (N)'	System	23 Sep 2020 12:17:51
	System	23 Sep 2020 12:17:51

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:17:46', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '83455e3f-4615-4004-95e7-6131b0daeeed' User entered 'No (N)'	System	23 Sep 2020 12:17:51
	System	23 Sep 2020 12:17:51

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:17:49', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '83455e3f-4615-4004-95e7-6131b0daeeed' User entered '23 Sep 2020 06:17'	System	23 Sep 2020 12:17:51
	System	23 Sep 2020 12:17:51

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:51', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9ce3ea28-d6dc-4d44-a32f-9d16ffa8a5ee'	System	16 Sep 2020 22:05:19
User entered 'None (1)'	System	16 Sep 2020 22:05:19

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9ce3ea28-d6dc-4d44-a32f-9d16ffa8a5ee' User entered 'No (N)'	System	16 Sep 2020 22:05:19
	System	16 Sep 2020 22:05:19

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:04:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9ce3ea28-d6dc-4d44-a32f-9d16ffa8a5ee' User entered 'No (N)'	System	16 Sep 2020 22:05:19
	System	16 Sep 2020 22:05:19

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:09', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9ce3ea28-d6dc-4d44-a32f-9d16ffa8a5ee' User entered 'None (1)'	System	16 Sep 2020 22:05:19
	System	16 Sep 2020 22:05:19

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '9ce3ea28-d6dc-4d44-a32f-9d16ffa8a5ee'	System	16 Sep 2020 22:05:19
User entered '16 Sep 2020 16:05'	System	16 Sep 2020 22:05:19

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 18:21'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:05', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '21067a02-73f9-47fa-9a55-8bd40a6ebec8' User entered 'None (1)'	System	17 Sep 2020 13:41:22
	System	17 Sep 2020 13:41:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '21067a02-73f9-47fa-9a55-8bd40a6ebec8' User entered 'No (N)'	System	17 Sep 2020 13:41:22
	System	17 Sep 2020 13:41:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:10', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '21067a02-73f9-47fa-9a55-8bd40a6ebec8' User entered 'No (N)'	System	17 Sep 2020 13:41:22
	System	17 Sep 2020 13:41:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:13', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '21067a02-73f9-47fa-9a55-8bd40a6ebec8' User entered 'None (1)'	System	17 Sep 2020 13:41:22
	System	17 Sep 2020 13:41:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:17', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '21067a02-73f9-47fa-9a55-8bd40a6ebec8' User entered '17 Sep 2020 07:41'	System	17 Sep 2020 13:41:22
	System	17 Sep 2020 13:41:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 19:16'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 2'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 3'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 4'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:07', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3784acff-5e3c-48b2-8680-0076ad0fd0cd'	System	20 Sep 2020 13:11:22
User entered 'None (1)'	System	20 Sep 2020 13:11:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:10', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3784acff-5e3c-48b2-8680-0076ad0fd0cd' User entered 'No (N)'	System	20 Sep 2020 13:11:22
	System	20 Sep 2020 13:11:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:13', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3784acff-5e3c-48b2-8680-0076ad0fd0cd' User entered 'No (N)'	System	20 Sep 2020 13:11:22
	System	20 Sep 2020 13:11:22



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3784acff-5e3c-48b2-8680-0076ad0fd0cd' User entered 'None (1)'	System	20 Sep 2020 13:11:22
	System	20 Sep 2020 13:11:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3784acff-5e3c-48b2-8680-0076ad0fd0cd' User entered '20 Sep 2020 07:11'	System	20 Sep 2020 13:11:22
	System	20 Sep 2020 13:11:22

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 5'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:03', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '22da08ee-af92-4473-84fe-a6d9f0aad097'	System	21 Sep 2020 14:01:40
User entered 'None (1)'	System	21 Sep 2020 14:01:40

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:12', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '22da08ee-af92-4473-84fe-a6d9f0aad097'	System	21 Sep 2020 14:01:40
User entered 'No (N)'	System	21 Sep 2020 14:01:40

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '22da08ee-af92-4473-84fe-a6d9f0aad097'	System	21 Sep 2020 14:01:40
User entered 'No (N)'	System	21 Sep 2020 14:01:40



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:21', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '22da08ee-af92-4473-84fe-a6d9f0aad097'	System	21 Sep 2020 14:01:40
User entered 'None (1)'	System	21 Sep 2020 14:01:40

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:38', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '22da08ee-af92-4473-84fe-a6d9f0aad097' User entered '21 Sep 2020 08:01'	System	21 Sep 2020 14:01:40
	System	21 Sep 2020 14:01:40

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 6'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:46', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5d082bbc-681a-455c-b8c2-03f1025e9380' User entered 'None (1)'	System	22 Sep 2020 12:01:03
	System	22 Sep 2020 12:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:48', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5d082bbc-681a-455c-b8c2-03f1025e9380' User entered 'No (N)'	System	22 Sep 2020 12:01:03
	System	22 Sep 2020 12:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:50', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5d082bbc-681a-455c-b8c2-03f1025e9380' User entered 'No (N)'	System	22 Sep 2020 12:01:03
	System	22 Sep 2020 12:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5d082bbc-681a-455c-b8c2-03f1025e9380' User entered 'None (1)'	System	22 Sep 2020 12:01:03
	System	22 Sep 2020 12:01:03

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:00:58', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5d082bbc-681a-455c-b8c2-03f1025e9380' User entered '22 Sep 2020 06:00'	System	22 Sep 2020 12:01:03
	System	22 Sep 2020 12:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 7'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:17:56', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '36d2ecd5-e42d-4833-b93d-c6d29d5940f6' User entered 'None (1)'	System	23 Sep 2020 12:18:15
	System	23 Sep 2020 12:18:15

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:01', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '36d2ecd5-e42d-4833-b93d-c6d29d5940f6' User entered 'No (N)'	System	23 Sep 2020 12:18:15
	System	23 Sep 2020 12:18:15

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '36d2ecd5-e42d-4833-b93d-c6d29d5940f6' User entered 'No (N)'	System	23 Sep 2020 12:18:15
	System	23 Sep 2020 12:18:15



US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:08', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '36d2ecd5-e42d-4833-b93d-c6d29d5940f6' User entered 'None (1)'	System	23 Sep 2020 12:18:15
	System	23 Sep 2020 12:18:15

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:11', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '36d2ecd5-e42d-4833-b93d-c6d29d5940f6' User entered '23 Sep 2020 06:18'	System	23 Sep 2020 12:18:15
	System	23 Sep 2020 12:18:15

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:23', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:31', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:33', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:36', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'None (0)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:57', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered 'No (N)'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-16T16:05:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3b23d465-c768-453e-96d9-ebc333704a24' User entered '16 Sep 2020 16:05'	System	16 Sep 2020 22:06:04
	System	16 Sep 2020 22:06:04

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 18:21'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:22', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:23', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:25', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:26', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:28', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'None (0)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:30', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered 'No (N)'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-17T07:41:32', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '73b093bd-71f9-4d9b-973f-b9880c5b07b4' User entered '17 Sep 2020 07:41'	System	17 Sep 2020 13:41:35
	System	17 Sep 2020 13:41:35



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '16 Sep 2020 19:16'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 2'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 3'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 4'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:48', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:50', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:51', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:53', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:55', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:57', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'None (0)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:11:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered 'No (N)'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08



**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-20T07:12:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '2c69dd21-7e08-488d-88a0-bfb15e039046' User entered '20 Sep 2020 07:12'	System	20 Sep 2020 13:12:08
	System	20 Sep 2020 13:12:08

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 5'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:42', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:44', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:47', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:51', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:52', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:01:54', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered 'None (0)'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:02:02', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692'	System	21 Sep 2020 14:02:11
User entered 'No (N)'	System	21 Sep 2020 14:02:11

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-21T08:02:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e168fcfd-8e23-41d3-b19a-c8358407d692' User entered '21 Sep 2020 08:02'	System	21 Sep 2020 14:02:11
	System	21 Sep 2020 14:02:11

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 6'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:02', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:03', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:06', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:07', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:09', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:12', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'None (0)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:14', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered 'No (N)'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-22T06:01:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5b7954d1-e13e-4c75-af33-5818855a84bd' User entered '22 Sep 2020 06:01'	System	22 Sep 2020 12:01:19
	System	22 Sep 2020 12:01:19

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 22:01:36



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	16 Sep 2020 22:01:36
User entered 'Day 7'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:14', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:16', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:18', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:19', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:21', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:22', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'None (0)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29



US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered 'No (N)'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

**US3142236**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:29:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-09-23T06:18:26', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '8cfc3e28-3092-4392-8081-591bff43b3ca' User entered '23 Sep 2020 06:18'	System	23 Sep 2020 12:18:29
	System	23 Sep 2020 12:18:29

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 22:01:36

US3142236

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 22:01:36

**US3142236**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:36:25

US3142236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '24 Sep 2020'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:36:25

US3142236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:36:25

US3142236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Dalia Jeronimo (b) (4) (b) (4)	25 Sep 2020 14:36:25



US3142236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:36:12

US3142236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	25 Sep 2020 14:36:12

US3142236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Oct 2020 16:57:26

US3142236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '30 Sep 2020'	Jami Wagner (b) (4)	06 Oct 2020 16:57:26

US3142236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	06 Oct 2020 16:57:26

US3142236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	06 Oct 2020 16:57:26

US3142236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Oct 2020 16:57:39

US3142236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	06 Oct 2020 16:57:39



**US3142236**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:30:07

US3142236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '7 Oct 2020'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:30:07

US3142236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:30:07

US3142236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:30:07

US3142236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:30:14

**US3142236**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	08 Oct 2020 15:30:14

US3142236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:04

US3142236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Oct 2020'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:04



US3142236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	22 Oct 2020 22:47:04

**US3142236**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'VISIT3'	System	22 Oct 2020 22:47:04

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Oct 2020'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:01'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '13 Oct 2020 15:01'	System	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '97.8' F	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39



US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '94'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'bpm'	System	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'breaths/min'	System	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '115'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '86'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:39



US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'mmHg'	System	22 Oct 2020 22:47:39

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27

US3142236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27

US3142236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:48

US3142236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Oct 2020'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:47:48

US3142236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:48:05

US3142236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Oct 2020'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:48:05

US3142236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:10'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:48:05



US3142236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered '13 Oct 2020 15:10'	System	22 Oct 2020 22:48:05

US3142236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 22:48:10

**US3142236**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	22 Oct 2020 22:48:10

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 64'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

Have you been exposed to someone with 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 18:58:24

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 71'	System	19 Aug 2020 18:58:24



US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-10-26T09:46:42', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5f03572a-3a34-474b-980e-f9bfc9bae7a0'	System	26 Oct 2020 15:46:52
User entered 'No (N)'	System	26 Oct 2020 15:46:52

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

Have you been exposed to someone with 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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-10-26T09:46:46', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5f03572a-3a34-474b-980e-f9bfc9bae7a0'	System	26 Oct 2020 15:46:52
User entered 'No (N)'	System	26 Oct 2020 15:46:52

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-10-26T09:46:50', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '5f03572a-3a34-474b-980e-f9bfc9bae7a0' User entered '26 Oct 2020 09:46:50'	System	26 Oct 2020 15:46:52
	System	26 Oct 2020 15:46:52

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 18:58:24

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 78'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-03T18:19:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd8368b37-b498-4073-8f24-b7159894604b' User entered 'No (N)'	System	04 Nov 2020 01:19:40
	System	04 Nov 2020 01:19:40

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

Have you been exposed to someone with 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 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-03T18:19:34', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd8368b37-b498-4073-8f24-b7159894604b' User entered 'No (N)'	System	04 Nov 2020 01:19:40
	System	04 Nov 2020 01:19:40



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-03T18:19:37', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd8368b37-b498-4073-8f24-b7159894604b' User entered '03 Nov 2020 18:19:37'	System	04 Nov 2020 01:19:40
	System	04 Nov 2020 01:19:40

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 18:58:24

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:01:03
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered 'Day 92'	System	19 Aug 2020 18:58:24

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Have you been exposed to someone with 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

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**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



**US3142236**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44



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

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

US3142236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

[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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Please 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 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

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**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44

**US3142236**

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

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 18:58:24

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:10:44
Data entry locked.	System	19 Aug 2020 18:58:24
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 18:58:24

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-20T07:03:59', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d7666ad-d68e-45b7-9655-7c18d1d5f031'	System	20 Nov 2020 14:04:13
User entered 'No (N)'	System	20 Nov 2020 14:04:13

US3142236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:11

Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-20T07:04:04', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d7666ad-d68e-45b7-9655-7c18d1d5f031'	System	20 Nov 2020 14:04:13
User entered 'No (N)'	System	20 Nov 2020 14:04:13

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-20T07:04:09', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d7666ad-d68e-45b7-9655-7c18d1d5f031' User entered '20 Nov 2020 07:04:09'	System	20 Nov 2020 14:04:13
	System	20 Nov 2020 14:04:13

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-28T17:51:41', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e0d6ba9a-3739-437f-b6d0-bc750014a649' User entered 'No (N)'	System	29 Nov 2020 00:51:51
	System	29 Nov 2020 00:51:51

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-28T17:51:45', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e0d6ba9a-3739-437f-b6d0-bc750014a649' User entered 'No (N)'	System	29 Nov 2020 00:51:51
	System	29 Nov 2020 00:51:51



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2020-11-28T17:51:49', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'e0d6ba9a-3739-437f-b6d0-bc750014a649' User entered '28 Nov 2020 17:51:49'	System	29 Nov 2020 00:51:51
	System	29 Nov 2020 00:51:51

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-08T19:53:20', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '4b625f32-1399-49af-a126-9ac52dfb0f9d' User entered 'No (N)'	System	09 Jan 2021 02:53:34
	System	09 Jan 2021 02:53:34

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-08T19:53:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '4b625f32-1399-49af-a126-9ac52dfb0f9d'	System	09 Jan 2021 02:53:34
User entered 'No (N)'	System	09 Jan 2021 02:53:34

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-08T19:53:28', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '4b625f32-1399-49af-a126-9ac52dfb0f9d' User entered '08 Jan 2021 19:53:28'	System	09 Jan 2021 02:53:34
	System	09 Jan 2021 02:53:34

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:11', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered 'Yes (Y)'	System	26 Jan 2021 19:34:54

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:15', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered 'No (N)'	System	26 Jan 2021 19:34:54

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:18', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered 'No (N)'	System	26 Jan 2021 19:34:54

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:24', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered 'Yes (Y)'	System	26 Jan 2021 19:34:54



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:29', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Jan 2021 19:34:54

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-01-26T11:14:33', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'd1a3b68e-0626-4b68-9da0-db91eb3bb877'	System	26 Jan 2021 19:34:54
User entered '26 Jan 2021 11:14:33'	System	26 Jan 2021 19:34:54

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:10:44



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:44:53-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '33b46574-a048-4ef7-99d1-a2c5bc4392d4' User entered 'No (N)'	System	16 Apr 2021 16:45:17
	System	16 Apr 2021 16:45:17

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:44:57-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '33b46574-a048-4ef7-99d1-a2c5bc4392d4' User entered 'No (N)'	System	16 Apr 2021 16:45:17
	System	16 Apr 2021 16:45:17



**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:45:02-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '33b46574-a048-4ef7-99d1-a2c5bc4392d4' User entered '16 Apr 2021 10:45:02'	System	16 Apr 2021 16:45:17
	System	16 Apr 2021 16:45:17

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:10:44

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-23T09:10:39-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c8336d64-6b53-4d8d-933f-3594ab3c2186'	System	23 Apr 2021 15:10:52
User entered 'No (N)'	System	23 Apr 2021 15:10:52

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-23T09:10:45-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c8336d64-6b53-4d8d-933f-3594ab3c2186'	System	23 Apr 2021 15:10:52
User entered 'No (N)'	System	23 Apr 2021 15:10:52

**US3142236**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-23T09:10:49-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: 'c8336d64-6b53-4d8d-933f-3594ab3c2186'	System	23 Apr 2021 15:10:52
User entered '23 Apr 2021 09:10:49'	System	23 Apr 2021 15:10:52

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-30T08:27:13-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d0836e0-4672-4958-8de5-89e1919cc078'	System	30 Apr 2021 14:27:24
User entered 'No (N)'	System	30 Apr 2021 14:27:24

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Have you been exposed to someone with 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 (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-30T08:27:18-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d0836e0-4672-4958-8de5-89e1919cc078'	System	30 Apr 2021 14:27:24
User entered 'No (N)'	System	30 Apr 2021 14:27:24

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-30T08:27:21-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '3d0836e0-4672-4958-8de5-89e1919cc078'	System	30 Apr 2021 14:27:24
User entered '30 Apr 2021 08:27:21'	System	30 Apr 2021 14:27:24

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:10:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:10:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:10:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:10:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:10:44



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:10:44



**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:10:44

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:10:44

**US3142236**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:44
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:10:44

US3142236

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:29:11**

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 12:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:45:46-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '93476d18-0128-4c0d-9354-833386bd37a0'	System	16 Apr 2021 16:46:23
User entered 'Yes (Y)'	System	16 Apr 2021 16:46:23

US3142236

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:29:11**

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 12:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:45:52-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '93476d18-0128-4c0d-9354-833386bd37a0'	System	16 Apr 2021 16:46:23
User entered 'Yes (Y)'	System	16 Apr 2021 16:46:23



**US3142236**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BE3B86F-A066-4BF4-B3A5-7092FF248308)', Time: '2021-04-16T10:45:59-06:00', User OID: 'PatientReportedOutcome (US3142236)', ODM File OID: '93476d18-0128-4c0d-9354-833386bd37a0' User entered '16 Apr 2021 10:45:59'	System	16 Apr 2021 16:46:23
	System	16 Apr 2021 16:46:23

US3142236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	11 Nov 2020 16:21:31

US3142236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 13NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:11:01
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 13NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' answered with 'done' (Site from DM).	Jami Wagner (b) (4)	01 Apr 2021 22:23:43
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 13NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:14:10
User entered '9 Nov 2020'	Jami Wagner (b) (4)	11 Nov 2020 16:21:31

US3142236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	11 Nov 2020 16:21:31

US3142236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	11 Nov 2020 16:21:31

US3142236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4)	11 Nov 2020 16:21:36
	(b) (4)	

**US3142236**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:27
User entered 'I'	System	11 Nov 2020 16:21:36

**US3142236**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Dec 2020 16:30:07



US3142236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14 Dec 2020'	Jami Wagner (b) (4)	15 Dec 2020 16:30:07

US3142236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	15 Dec 2020 16:30:07

US3142236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4)	15 Dec 2020 16:30:07
	(b) (4)	

US3142236

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Dec 2020 16:30:13

**US3142236**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User entered 'I'	System	15 Dec 2020 16:30:13

**US3142236**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	13 Jan 2021 17:47:27

US3142236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	13 Jan 2021 17:47:27

US3142236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	13 Jan 2021 17:47:27



US3142236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	13 Jan 2021 17:47:27

US3142236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	13 Jan 2021 17:47:32

US3142236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User entered 'I'	System	13 Jan 2021 17:47:32

**US3142236**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	19 Feb 2021 16:53:10

US3142236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Feb 2021'	Jami Wagner (b) (4)	19 Feb 2021 16:53:10

US3142236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	19 Feb 2021 16:53:10

US3142236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	19 Feb 2021 16:53:10

US3142236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	19 Feb 2021 16:53:22



US3142236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:24
User entered 'I'	System	19 Feb 2021 16:53:22

US3142236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:29:55

US3142236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '25 Mar 2021'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:29:55

US3142236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	25 Mar 2021 22:29:55

**US3142236**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered 'VISIT4'	System	25 Mar 2021 22:29:55

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01



US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered empty.	System	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered empty.	System	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered empty.	System	05 Apr 2021 19:48:01



US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered empty.	System	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered empty.	System	05 Apr 2021 19:48:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04

US3142236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04

US3142236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:01

US3142236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:01



US3142236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:14

US3142236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '25 Mar 2021'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:14

US3142236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:04'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:14

US3142236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered '25 Mar 2021 16:04'	System	25 Mar 2021 22:30:14

US3142236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:19

US3142236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:04
User entered 'I'	System	25 Mar 2021 22:30:19

US3142236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	16 Apr 2021 16:50:27
	(b) (4)	

US3142236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered '16 Apr 2021'	Lisa Jackson (b) (4)	16 Apr 2021 16:50:27
	(b) (4)	



US3142236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	16 Apr 2021 16:50:27

US3142236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Initial contact was made on the 12APR2021. Follow up was done 16APR2021'	(b) (4) Lisa Jackson (b) (4)	16 Apr 2021 16:50:27

US3142236

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	16 Apr 2021 16:50:53
	(b) (4)	

**US3142236**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:50:53

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 20:12:10
User closed query 'Data is required. Please complete.' (Site from System).	Shelby Pickle (b) (4)	25 Aug 2020 13:54:47
Query 'Data is required. Please complete.' answered with 'Entered in error' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 20:07:28
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:07:17
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4)	19 Aug 2020 20:07:17
User entered '19 Aug 2020'	(b) (4)	19 Aug 2020 19:52:26

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Aug 2020 13:54:49
Query 'Data is required. Please complete.' answered with 'Opened in error' (Site from System).	Shelby Pickle (b) (4)	19 Aug 2020 20:07:34
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:07:17
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4)	19 Aug 2020 20:07:17
User entered '13:40'	Shelby Pickle (b) (4)	19 Aug 2020 19:52:26

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:22
User entered empty.	System	19 Aug 2020 20:07:17
User entered '19 Aug 2020 13:40'	System	19 Aug 2020 19:52:26

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	(b) (4)	
	Shelby Pickle (b) (4)	23 Nov 2020 20:12:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 13:54:51
Query 'Data is required. Please complete.' answered with 'Opened in error' (Site from System).	Shelby Pickle (b) (4)	19 Aug 2020 20:07:40
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:07:17
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4)	19 Aug 2020 20:07:17
	(b) (4)	
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Shelby Pickle (b) (4)	19 Aug 2020 19:52:26
	(b) (4)	



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Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Shelby Pickle (b) (4)	23 Nov 2020 20:12:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 13:54:53
Query 'Data is required. Please complete.' answered with 'Opened in error' (Site from System).	Shelby Pickle (b) (4)	19 Aug 2020 20:07:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:07:17
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4)	19 Aug 2020 20:07:17
	(b) (4)	
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	19 Aug 2020 19:52:26
	(b) (4)	

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 1 (Day 1)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '10 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:13:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 2 (Day 2)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '11 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:17:50

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 3 (Day 3)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '12 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	Shelby Pickle (b) (4)	23 Nov 2020 20:18:41



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:18:41

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 4 (Day 4)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '13 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:20:27



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '99.1' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:20:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 5 (Day 5)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '14 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98.4' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:22:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 6 (Day 6)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '15 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'I'	Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered empty.	System	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43



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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:29:43

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 7 (Day 7)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '16 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00



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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:31:00

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Form: Symptom Log (8)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98.0' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00



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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:31:00

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 8 (Day 8)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '17 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '99'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:32:27



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98.0' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Moderate (Moderate)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:32:27

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Day 9 (Day 9)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '18 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:33:39

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97.9' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:33:39

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'Per CDM: Log line #10 (Day 9) is the same as log line #11. Please reconcile or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:14:06
Query 'Per CDM: Log line #10 (Day 9) is the same as log line #11. Please reconcile or else clarify.'	Jami Wagner (b) (4)	01 Apr 2021 22:22:54
answered with 'done' (Site from DM).	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Jami Wagner (b) (4)	01 Apr 2021 22:22:48
User opened query 'Per CDM: Log line #10 (Day 9) is the same as log line #11. Please reconcile or else clarify.' (Site from DM).	(b) (4)	
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	15 Mar 2021 22:33:42
	Shelby Pickle (b) (4)	23 Nov 2020 20:36:20
	(b) (4)	



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '19 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '97.6' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:36:20

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query ' Per CDM: On the log line number 11 and 12 the symptom day is mentioned as "Day 10". However dates are different on both the logs. Kindly review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:32:27
Query ' Per CDM: On the log line number 11 and 12 the symptom day is mentioned as "Day 10". However dates are different on both the logs. Kindly review and update accordingly.' answered with 'updated per query' (Site from DM).	Jill York (b) (4)	20 Apr 2021 23:18:04
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Jill York (b) (4)	20 Apr 2021 23:17:56
User opened query ' Per CDM: On the log line number 11 and 12 the symptom day is mentioned as "Day 10". However dates are different on both the logs. Kindly review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:28:43
Query 'Per CDM: On the log line number 11 and 12 the symptom day is mentioned as "Day 10". However dates are different. Kindly review and update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:27:09
User opened query 'Per CDM: On the log line number 11 and 12 the symptom day is mentioned as "Day 10". However dates are different. Kindly review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:26:45
User entered 'Day 10 (Day 10)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:38:05

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '20 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '0'	Shelby Pickle (b) (4)	23 Nov 2020 20:38:05



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User entered '%'	System	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered '98.0' F	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'Mild (Mild)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05



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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

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Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05



US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:29:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User entered 'None (None)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:05

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered '13 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

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Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

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Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered '13 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33



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Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

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Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:11

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:40
User entered '0'	System	23 Nov 2020 20:38:33

US3142236

Folder: Covid-19 Assessment 14 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:29:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:48
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:38:39

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:22
	(b) (4)	



**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:22
	(b) (4)	

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22



US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:22
	(b) (4)	

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:22
	(b) (4)	

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:11

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:22
	(b) (4)	

US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:11

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22



US3142236

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

**US3142236**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Shelby Pickle (b) (4) (b) (4)	23 Nov 2020 20:40:22

US3142236

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered 'SICKD1'	System	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45



US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Nov 2020'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Nov 2020 16:24:10
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 20:39:53
User opened query 'Data is required. Please provide.' (Site from System).	Shelby Pickle (b) (4)	23 Nov 2020 20:39:45
User entered empty.	System	23 Nov 2020 20:39:45
	Shelby Pickle (b) (4)	23 Nov 2020 20:39:45
	(b) (4)	

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered empty.	System	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:39:04

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '99.1' F	Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45



US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '85'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered 'bpm'	System	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered 'breaths/min'	System	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '120'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered 'mmHg'	System	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '91'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:39:45

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User entered 'mmHg'	System	23 Nov 2020 20:39:45



US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37

US3142236

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37

US3142236

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:40:03

US3142236

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13 Nov 2020'	Shelby Pickle (b) (4)	23 Nov 2020 20:40:03

US3142236

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:29:11

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:40:08

US3142236

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:29:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Shelby Pickle (b) (4)	23 Nov 2020 20:40:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:38:18

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	(b) (4) Jami Wagner (b) (4)	12 Jan 2021 22:38:18
	(b) (4)	



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4)	12 Jan 2021 22:38:18

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 22:38:18

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	(b) (4) Jami Wagner (b) (4)	12 Jan 2021 22:39:04
	(b) (4)	

**US3142236**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:11**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	Jami Wagner (b) (4)	09 Apr 2021 19:22:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:08:31

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:21
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 19:23:21
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:22:57
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:41:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:08:31

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:26:51
Query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'Data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:23:32
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:22:57
User opened query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:37:22
User entered 'mRNA-1273 (mRNA-1273)'	Jami Wagner (b) (4) (b) (4)	12 Jan 2021 22:39:04



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:44:54
User entered 'Placebo (Placebo)'	Jami Wagner (b) (4)	12 Jan 2021 22:39:04
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:44:54
User entered 'Placebo (Placebo)'	Jami Wagner (b) (4)	12 Jan 2021 22:39:04
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '1'	System	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:29:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'I'	System	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '79' in	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '255.8' lb	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '28.87728'	System	15 Jan 2021 16:59:21
DataPoint set to visible.	System	12 Jan 2021 22:39:04



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '79' in	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '255.8' lb	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '28.87728'	System	15 Jan 2021 16:59:21
DataPoint set to visible.	System	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User accepted default value 'Pre-Dose (PREDOSE)'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14:56'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '12 Jan 2021 14:56'	System	15 Jan 2021 16:59:21



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '98.0' F	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'temporal'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '85'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'bpm'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'breaths/min'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '110'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '82'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '79' in	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '255.8' lb	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '28.87728'	System	15 Jan 2021 16:59:21
DataPoint set to visible.	System	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User accepted default value 'Post-Dose (POSTDOSE)'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:11'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '12 Jan 2021 16:11'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
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).	(b) (4)	
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.'	System	15 Jan 2021 16:59:38
answered by data change (Site from System).		
User entered '97.9' F reason for change: Data Entry Error	System	15 Jan 2021 16:59:38
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).	Jami Wagner (b) (4)	15 Jan 2021 16:59:38
User entered '95.9' F	(b) (4)	
	System	15 Jan 2021 16:59:21
	Jami Wagner (b) (4)	15 Jan 2021 16:59:21
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'temporal'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '74'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'bpm'	System	15 Jan 2021 16:59:21



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'breaths/min'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '136'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '82'	Jami Wagner (b) (4)	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	15 Jan 2021 16:59:21

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:41:18

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 22:41:18



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).		19 Apr 2021 07:27:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	(b) (4) System	15 Apr 2021 00:23:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	15 Apr 2021 00:23:17
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' answered with 'added' (Site from DM).	Jill York (b) (4)	15 Apr 2021 00:23:07
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	15 Apr 2021 00:22:54
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 03:49:52
User entered 'No (N)'	Jami Wagner (b) (4)	01 Apr 2021 22:07:44
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Jill York (b) (4)	15 Apr 2021 00:22:54
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:07:44
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 00:23:33
User entered 'Urine (URINE)' reason for change: Data Entry Error	Jill York (b) (4)	15 Apr 2021 00:23:33
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Apr 2021 00:23:17
User entered empty.	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:07:44

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Jill York (b) (4)	15 Apr 2021 00:22:54
	Jami Wagner (b) (4)	01 Apr 2021 22:07:44
	(b) (4)	

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	15 Apr 2021 00:22:54
User entered empty.	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:07:44

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:07:44

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:07:44

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	01 Apr 2021 22:07:44



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mRNA-1273'	System	12 Jan 2021 22:42:08
DataPoint set to visible.	System	12 Jan 2021 22:39:04

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:29'	Jami Wagner (b) (4)	12 Jan 2021 22:42:08

**US3142236**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '12 Jan 2021 15:29'	System	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Left Arm (LEFT ARM)'	Jami Wagner (b) (4)	12 Jan 2021 22:42:08



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'ONCE'	System	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 22:42:08

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:39:42

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 22:39:42

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:00'	Jami Wagner (b) (4)	12 Jan 2021 22:39:42

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '12 Jan 2021 15:00'	System	12 Jan 2021 22:39:42

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:40:26

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '12 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 22:40:26



US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:00'	Jami Wagner (b) (4)	12 Jan 2021 22:40:26

**US3142236**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '12 Jan 2021 15:00'	System	12 Jan 2021 22:40:26

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 22:40:47

US3142236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'I'	System	12 Jan 2021 22:40:47

**US3142236**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	21 Jan 2021 23:57:46

US3142236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '20 Jan 2021'	Jami Wagner (b) (4)	21 Jan 2021 23:57:46

US3142236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	21 Jan 2021 23:57:46

US3142236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	21 Jan 2021 23:57:46



**US3142236**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	21 Jan 2021 23:57:50

**US3142236**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User entered 'I'	System	21 Jan 2021 23:57:50

US3142236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User entered '1'	System	21 Jan 2021 23:57:50
DataPoint set to visible.	System	21 Jan 2021 23:57:50

US3142236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:50:08

**US3142236**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:50:08

US3142236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[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 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:50:08

**US3142236**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'OLD29'	System	18 Feb 2021 23:50:08

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User accepted default value 'Pre-Dose (PREDOSE)'		18 Feb 2021 23:51:40



US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 23:51:40

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '15:57'	(b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '18 Feb 2021 15:57'	System	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '91'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40



**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'bpm'	System	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '14'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'breaths/min'	System	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '118'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '88'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	18 Feb 2021 23:51:40

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User accepted default value 'Post-Dose (POSTDOSE)'		18 Feb 2021 23:53:11



US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:40'	(b) (4), (b) (6)	18 Feb 2021 23:53:11

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '18 Feb 2021 16:40'	System	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '97.5' F	(b) (4), (b) (6)	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11

**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '81'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11



**US3142236**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'bpm'	System	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'breaths/min'	System	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '136'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '92'	(b) (4), (b) (6)	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mmHg'	System	18 Feb 2021 23:53:11

US3142236

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 23:53:35



**US3142236**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:53:35

US3142236

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).		19 Apr 2021 07:28:21
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 21:37:06
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' answered with 'updated' (Site from DM).	Jill York (b) (4)	15 Apr 2021 00:24:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	15 Apr 2021 00:24:20
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 03:48:38
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:08:03

US3142236

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Jill York (b) (4)	15 Apr 2021 00:24:20
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:08:03
	(b) (4)	

US3142236

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4)	
	Jill York (b) (4)	15 Apr 2021 00:24:20
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:08:03
	(b) (4)	

**US3142236**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Jill York (b) (4)	15 Apr 2021 00:24:20
	Jami Wagner (b) (4)	01 Apr 2021 22:08:03
	(b) (4)	

US3142236

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Jill York (b) (4)	15 Apr 2021 00:24:20
	Jami Wagner (b) (4)	01 Apr 2021 22:08:03
	(b) (4)	

**US3142236**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:08:03

**US3142236**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 22:08:03



**US3142236**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered empty.	System	01 Apr 2021 22:08:03

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:06

**US3142236**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:11**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'mRNA-1273'	System	18 Feb 2021 23:56:06
DataPoint set to visible.	System	21 Jan 2021 23:57:50

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:06

**US3142236**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:11**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:19'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered '18 Feb 2021 16:19'	System	18 Feb 2021 23:56:06



US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'ONCE'	System	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 23:56:06

US3142236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 23:56:12

US3142236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:26:15
User entered 'I'	System	18 Feb 2021 23:56:12

**US3142236**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Lisa Jackson (b) (4)	18 Mar 2021 22:30:56

US3142236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:42:27
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) (b) (4)	18 Mar 2021 22:31:15
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	18 Mar 2021 22:30:56
User entered '01 Mar 2021'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 22:30:56

**US3142236**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Jackson (b) (4)	18 Mar 2021 22:30:56



US3142236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Lisa Jackson (b) (4)	18 Mar 2021 22:30:56

US3142236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Lisa Jackson (b) (4)	18 Mar 2021 22:31:26

**US3142236**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:00
User entered 'I'	System	18 Mar 2021 22:31:26

US3142236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:30:35

US3142236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '25 Mar 2021'	Shelby Pickle (b) (4)	25 Mar 2021 22:30:35

US3142236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	25 Mar 2021 22:30:35

**US3142236**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered 'OLD57'	System	25 Mar 2021 22:30:35

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:33



US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '25 Mar 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:05'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Mar 2021 22:32:33

**US3142236**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered '25 Mar 2021 16:05'	System	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '99.3' F	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	Shelby Pickle (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '83'	Shelby Pickle (b) (4)	25 Mar 2021 22:32:33

**US3142236**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered 'bpm'	System	25 Mar 2021 22:32:33



US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered 'breaths/min'	System	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '100'	Shelby Pickle (b) (4)	25 Mar 2021 22:32:33

**US3142236**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered 'mmHg'	System	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '90'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Mar 2021 22:32:33

US3142236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered 'mmHg'	System	25 Mar 2021 22:32:33

**US3142236**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47

**US3142236**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47



US3142236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'No (N)'	Shelby Pickle (b) (4)	25 Mar 2021 22:32:47

US3142236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered empty.	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:47

US3142236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:59

US3142236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '25 Mar 2021'	(b) (4) Shelby Pickle (b) (4)	25 Mar 2021 22:32:59

US3142236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:04'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Mar 2021 22:32:59

**US3142236**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:23:47
User entered '25 Mar 2021 16:04'	System	25 Mar 2021 22:32:59

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:29:11

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '20 Jan 2021'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:06:39

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:29:11

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:06:39



**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:29:11**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:06:39

US3142236

Folder: **Unscheduled 20 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 15:29:11**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:06:39

**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:29:11**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '0'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:06:39

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '20 Jan 2021'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '16:09'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User entered '20 Jan 2021 16:09'	System	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '97.5' F	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49



US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '90'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User entered 'bpm'	System	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '13'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User entered 'breaths/min'	System	21 Jan 2021 21:07:49

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '130'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User entered 'mmHg'	System	21 Jan 2021 21:07:49



US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '90'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:07:49

**US3142236**

**Folder: Unscheduled 20 Jan 2021**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21
User entered 'mmHg'	System	21 Jan 2021 21:07:49

US3142236

Folder: **Unscheduled 20 Jan 2021**

Form: **Vital Signs**

Generated On: **09 Jun 2021 15:29:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:21

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:08:19

US3142236

Folder: Unscheduled 20 Jan 2021

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '20 Jan 2021'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 21:08:19

**US3142236**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:29:11**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 20:51:38

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:07
DataPoint Un-verified.		17 Feb 2021 20:44:21
DataPoint Verified.		17 Feb 2021 20:43:58
User entered 'USA-US064-2021-mRNA-1273-P301000003'	System	22 Jan 2021 17:56:42
User entered 'New'	(b) (4), (b) (6)	22 Jan 2021 17:56:42



US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 20:44:16
DataPoint Verified.		17 Feb 2021 20:44:00
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Paresthesia upper limb - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 21:10:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 21:10:07
Data point term sent to Coder	System	21 Jan 2021 20:54:13
User entered 'Left Arm Paresthesia'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:44:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Since the symptoms began on 20 Jan 2021, please consider updating start date to 20 Jan 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:16:48
Query 'PV Query: Since the symptoms began on 20 Jan 2021, please consider updating start date to 20 Jan 2021.' answered with 'Updated' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:14:10
User entered '20 Jan 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:14:03
User opened query 'PV Query: Since the symptoms began on 20 Jan 2021, please consider updating start date to 20 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:49:36
User entered '21 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

**US3142236**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:11**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

**US3142236**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 20:53:39

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 22:10:44
User entered 'No (N)' reason for change: Data Entry Error	Jami Wagner (b) (4)	01 Apr 2021 22:10:44
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 22:10:27
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:14:10
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'done' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:12:09
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Apr 2021 22:10:27
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	01 Apr 2021 22:10:27
User entered '22 Jan 2021' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:10:27
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Mar 2021 18:15:59
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Jan 2021 13:19:56
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

**US3142236**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 20:53:39

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:44:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 03:56:37
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient hospitalization ongoing' (Site from System).	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:58:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	21 Jan 2021 20:53:39
User entered 'I'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:14:27
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'subject was not hospitalized overnight but event was considered medically important. Unable to change SAE report and site is working with Medidata on this' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:11:53
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 21:03:46
User entered '21 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:00
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Added' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:14:51
User entered '21 Jan 2021' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:14:38
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Jan 2021 13:19:29
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:44:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:44:51
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug and study procedure.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:14:32
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug and study procedure.' answered with 'Event occurred within 24 hours of receiving fist dose of IP, same laterality of dose, and it was assessed by the ED as a histamine response' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:13:58
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug and study procedure.' (Site from Safety).	(b) (4), (b) (6)	30 Jan 2021 13:19:19
User entered 'Related (RELATED)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered 'Related (RELATED)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

US3142236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'Per CDM: V1D1 is recorded as 19Aug2020 and V2D29 is recorded as 16Sep2020 (29 days after dose 1) which is within visit window. Therefore, per page 51 of CCGs v5.0, it is unexpected the "Action taken with IP" to be "Dose Delayed". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:09:26
Query 'Per CDM: V1D1 is recorded as 19Aug2020 and V2D29 is recorded as 16Sep2020 (29 days after dose 1) which is within visit window. Therefore, per page 51 of CCGs v5.0, it is unexpected the "Action taken with IP" to be "Dose Delayed". Please review and reconcile. Thank you.	Jill York (b) (4)	20 Apr 2021 23:16:42
' answered with 'DM to check dates as this query does not make sense. The second dose of open label was delayed.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:14:21
User opened query 'Per CDM: V1D1 is recorded as 19Aug2020 and V2D29 is recorded as 16Sep2020 (29 days after dose 1) which is within visit window. Therefore, per page 51 of CCGs v5.0, it is unexpected the "Action taken with IP" to be "Dose Delayed". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:14:36
User closed query 'PV Query: As action taken with study drug was dose delayed, please provide rechallenge for event of left arm paresthesia.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 22:15:33
Query 'PV Query: As action taken with study drug was dose delayed, please provide rechallenge for event of left arm paresthesia.' answered with 'Subject received 2nd dose of IP however, subject was treated prophylactically with antihistamines prior to dosing' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	19 Mar 2021 21:03:32
User opened query 'PV Query: As action taken with study drug was dose delayed, please provide rechallenge for event of left arm paresthesia.' (Site from Safety).	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Action taken with investigational product is "Investigational Product Withdrawn" However the subject was dosed on Visit 2 Day 29 under Exposure form. Please review the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:26:45
Query 'Per CDM: Action taken with investigational product is "Investigational Product Withdrawn" However the subject was dosed on Visit 2 Day 29 under Exposure form. Please review the data else clarify. Thank you.' answered with 'Corrected' (Site from DM).	Shelby Pickle (b) (4)	09 Mar 2021 18:15:40
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 18:15:24
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Meghan York (b) (4)	28 Jan 2021 17:59:26
User entered 'None (NONE)' reason for change: Data Entry Error	Meghan York (b) (4)	28 Jan 2021 17:59:02
User opened query 'Per CDM: Action taken with investigational product is "Investigational Product Withdrawn" However the subject was dosed on Visit 2 Day 29 under Exposure form. Please review the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:26:03
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

None

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:14:33
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'correct as entered, no treatment given' (Site from DM).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:16:49
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 05:44:53
User entered 'I'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 02:44:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:09:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:15:59
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	30 Jan 2021 13:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 21:00:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 21:00:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 21:00:39
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 20:53:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
	(b) (4)	
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 20:53:39
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:44:51
User closed query 'PV Query: Please confirm if subject received second dose of mRNA-1273.' (Site from Safety).	(b) (4)	02 Apr 2021 12:14:51
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:14:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		02 Apr 2021 12:14:45
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory or diagnostic exam results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).		02 Apr 2021 12:14:41
User closed query 'Per DM CLR: Narrative = PATIENT EXPERIENCE SWELLING, REDNESS AND TENDERNESS AT THE INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		02 Apr 2021 07:14:40
Query 'Per DM CLR: Narrative = PATIENT EXPERIENCE SWELLING, REDNESS AND TENDERNESS AT THE INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'due to these being solicited reactions, and they did not last beyond 7 days, this was not reported as an AE' (Site from DM).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:20:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if subject received second dose of mRNA-1273.' answered with 'yes-subject did end up receiving second dose' (Site from Safety).	Jami Wagner (b) (4)	01 Apr 2021 22:19:19
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'no known covid testing or results' (Site from Safety).	Jami Wagner (b) (4)	01 Apr 2021 22:18:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment provided' (Site from Safety).	Jami Wagner (b) (4)	01 Apr 2021 22:18:25
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory or diagnostic exam results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'subject was not hospitalized however site is working with medidata to correct' (Site from Safety).	Jami Wagner (b) (4)	01 Apr 2021 22:18:07
User opened query 'Per DM CLR: Narrative = PATIENT EXPERIENCE SWELLING, REDNESS AND TENDERNESS AT THE INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 05:45:21
User opened query 'PV Query: Please confirm if subject received second dose of mRNA-1273.' (Site from Safety).		19 Mar 2021 21:04:04
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		19 Mar 2021 21:03:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:11

[Narrative](#)

Audit	User	Time (GMT)
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)	30 Jan 2021 13:20:24
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory or diagnostic exam results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).		30 Jan 2021 13:19:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 21:00:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Jan 2021 21:00:39
User entered 'Patient experience swelling, redness and tenderness at the injection site. Patient came in for an unscheduled visit 20Jan2021 and was assessed by sub investigator. The patient and doctor discussed possible steroids or antibiotics if symptoms worsened, but patient declined starting treatment 20Jan2021. Patient went to the Emergency Room on 21Jan2021 due to Left side pain and paresthesia.' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 21:00:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 20:53:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 20:53:39

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 20:53:39

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 20:53:39

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 20:53:39

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 15:29:11**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:03:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:05:41
Data point term sent to Coder	System	23 Oct 2020 16:05:05
User entered 'Zyzal'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:04:21



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'seasonal allergies'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '1'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'tablet (TABLET)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:04:21

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'as needed (PRN)'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Oral (ORAL)'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2000'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:04:21
	(b) (4)	

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:04:21

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:04:21



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:04:21

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:06:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:06:29
Data point term sent to Coder	System	23 Oct 2020 16:06:06
User entered 'botox'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:05:26

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'migraines'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'I'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Other (OTHER)'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Ingection'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'other (OTHER)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:05:26



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'once every 10 weeks'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:05:26

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2018'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:05:26
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:05:26

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:05:26

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:05:26

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 05:55:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:55:22
Data point term sent to Coder	System	23 Oct 2020 16:07:09
User entered 'Spiranolactone'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:06:17

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 04:06:48
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added to mh page ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 18:33:45
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:40:36
User entered 'ACne'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:06:17

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '100'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'mg (mg)'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'once daily (QD)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Oral (ORAL)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2015'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:06:17
	(b) (4)	

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:06:17

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:06:17

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:06:17

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Nov 2020 02:01:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:01:46
Data point term sent to Coder	System	23 Oct 2020 16:08:10
User entered 'Adcleral C'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:07:18

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Obsessive Compulsive Disorder'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:07:18



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '30'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'mg (mg)'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'once daily (QD)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Oral (ORAL)'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2005'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:07:18
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:07:18

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:07:18

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:07:18

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE SODIUM, PRODUCTSYNONYM: CYTOMEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:09:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:09:30
Data point term sent to Coder	System	23 Oct 2020 16:08:11
User entered 'Cytomel'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:08:05



US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Hypothyroidism'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '5'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Other (OTHER)'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'mcg'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'once daily (QD)'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Oral (ORAL)'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2002'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:08:05
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:08:05

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:08:05

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:08:05



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:08:05

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:11:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:11:36
Data point term sent to Coder	System	23 Oct 2020 16:10:13
User entered 'Levothyroxine'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:09:13

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Hypothyroidism'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '112'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Other (OTHER)'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'mcg'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'once daily (QD)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:09:13



US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Oral (ORAL)'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 1996'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:09:13
	(b) (4)	



**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:09:13

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:09:13

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:09:13

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:11:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:11:36
Data point term sent to Coder	System	23 Oct 2020 16:10:14
User entered 'Vitamin B12'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 04:11:55
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 18:34:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 18:33:59
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:41:18
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'General health'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '1000'	Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:13:43
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'done' (Site from DM).	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:21:16
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:21:01
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:31:23
User entered 'IU (IU)'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06



US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	01 Apr 2021 22:21:10
User entered 'mcg' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	01 Apr 2021 22:21:10
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	01 Apr 2021 22:21:01
User entered empty.	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'other (OTHER)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered '2 times monthly'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Meghan York (b) (4) (b) (4)	23 Oct 2020 16:10:06

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 2014'	Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	



US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered empty.	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:10:06
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:10:06

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:10:06

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:10:06

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:10:06

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: DEPO PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 16:11:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 16:11:38
Data point term sent to Coder	System	23 Oct 2020 16:11:15
User entered 'Depo Provera'	Meghan York (b) (4)	23 Oct 2020 16:11:09

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4)	09 Dec 2020 22:31:43
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User closed query 'Per CDM: Indication for medication is reported as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 05:02:36
Query 'Per CDM: Indication for medication is reported as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. Thank you.' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	09 Dec 2020 22:31:51
User opened query 'Per CDM: Indication for medication is reported as BIRTH CONTROL, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:30:45
User entered 'birth control'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:11:09



US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'unknown'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Other (OTHER)'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'unknown'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'other (OTHER)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'every 3 months'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'un UNK 1998'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	



US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

US3142236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	23 Oct 2020 16:11:09
	(b) (4)	

**US3142236**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:11:09

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:11:09

US3142236

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:29:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:11:09

US3142236

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:29:11**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:43:58
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 21:08:11
	(b) (4)	



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4)	01 Mar 2021 23:43:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).		29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.		10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).		02 Mar 2021 00:07:50

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:07:24
		02 Mar 2021 00:06:27
		02 Mar 2021 00:03:37
		01 Mar 2021 23:43:28
		01 Mar 2021 23:11:13
		01 Mar 2021 23:06:38
		01 Mar 2021 23:03:28
		01 Mar 2021 23:03:28
User closed query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).		

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US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System	22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York (b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:23:27
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4)	03 Mar 2021 21:57:37
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:23
DataPoint Un-verified.		01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 00:07:50

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:07:24
		02 Mar 2021 00:06:27
		02 Mar 2021 00:03:37
		01 Mar 2021 23:43:28
		01 Mar 2021 23:11:13
		01 Mar 2021 23:06:38
		01 Mar 2021 23:03:28
		01 Mar 2021 23:03:28

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User		Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York	(b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System		22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York	(b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York	(b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)		17 Feb 2021 20:23:27
Reviewed for Safety.	(b) (4), (b) (6)		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System		22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:57:37
DataPoint Un-verified.		01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42



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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55

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Form: Safety Report Form (1)

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Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User closed query 'Please reconcile start date with source documents' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 23:59:14
DataPoint Verified.		29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Query 'Please reconcile start date with source documents' answered with 'This would correspond to date of submission not the start date.' (Site from CRA).	(b) (4) Shelby Pickle (b) (4)	09 Mar 2021 18:20:40
User opened query 'Please reconcile start date with source documents' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:17:02
User entered '22/Jan/2021 12:56'	System	22 Jan 2021 17:56:55

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Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:29:11

**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)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:00
User entered 'I'		22 Jan 2021 17:56:55

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:23
DataPoint Un-verified.		01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).		29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.		10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).		02 Mar 2021 00:07:50

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 00:07:24
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA).		02 Mar 2021 00:06:27
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records.		02 Mar 2021 00:03:37
The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.		01 Mar 2021 23:43:28
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records.		01 Mar 2021 23:11:13
The AE SD log does not list an AE the event for the dates listed below.' (Site from CRA).		
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' canceled (Site from CRA).		01 Mar 2021 23:06:38
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' (Site from CRA).		01 Mar 2021 23:03:28
User closed query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).		01 Mar 2021 23:03:28

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System	22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York (b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:23:27
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:57:37
DataPoint Un-verified.		01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42



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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

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**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55



**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '29/Jan/2021 15:11'	(b) (4) System	29 Jan 2021 15:11:43

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Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:29:11

**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)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
User entered '1'		29 Jan 2021 15:11:43

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

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**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

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**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:23
DataPoint Un-verified.		01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 00:07:50

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:07:24
		02 Mar 2021 00:06:27
		02 Mar 2021 00:03:37
		01 Mar 2021 23:43:28
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' (Site from CRA). User closed query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).		01 Mar 2021 23:11:13
		01 Mar 2021 23:06:38
		01 Mar 2021 23:03:28
		01 Mar 2021 23:03:28

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System	22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York (b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:23:27
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:57:37
DataPoint Un-verified.		01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '09/Mar/2021 11:19'	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:29:11

**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)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:17:42
User entered '0'		10 Mar 2021 14:18:11

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:23
DataPoint Un-verified.		01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4)	29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.	(b) (4)	10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	(b) (4)	
	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
	(b) (4)	
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
	(b) (4)	
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
	(b) (4)	
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
	(b) (4)	
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
	(b) (4)	
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4)	02 Mar 2021 00:07:50

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:07:24
		02 Mar 2021 00:06:27
		02 Mar 2021 00:03:37
		01 Mar 2021 23:43:28
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' (Site from CRA). User closed query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).		01 Mar 2021 23:11:13
		01 Mar 2021 23:06:38
		01 Mar 2021 23:03:28
		01 Mar 2021 23:03:28

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System	22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York (b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:23:27
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:57:37
DataPoint Un-verified.		01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42



US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55



**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '10/Mar/2021 09:18'	(b) (4) System	10 Mar 2021 14:18:11

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:29:11

**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)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 12:17:42
User entered 'I'		10 Mar 2021 14:18:11

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:20
DataPoint Un-verified.		01 Mar 2021 23:18:35
DataPoint Verified.		17 Feb 2021 20:14:05
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'USA-US064-2021-MRNA-1273-P301000003'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:21
DataPoint Un-verified.		01 Mar 2021 23:18:25
DataPoint Verified.		17 Feb 2021 20:14:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:26
DataPoint Un-verified.		01 Mar 2021 23:18:26
DataPoint Verified.		17 Feb 2021 20:14:09
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:23
DataPoint Un-verified.		01 Mar 2021 23:18:28
DataPoint Verified.		17 Feb 2021 20:14:13
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 23:57:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User closed query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 16:39:43
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:55
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:55
Query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' answered with 'Trying to change but it doesnt seem to be saving the change.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:19:44
User entered 'Yes (Y)'	System	09 Mar 2021 18:19:29
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'Yes (Y)'	System	09 Mar 2021 18:17:04
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:16:49
User entered 'Yes (Y)'	System	09 Mar 2021 18:16:39
DataPoint Un-verified.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'SAE log notes "Yes" for criteria met but the criteria (1-5) is not specified.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:37
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 00:07:50

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. ' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:07:24
		02 Mar 2021 00:06:27
		02 Mar 2021 00:03:37
		01 Mar 2021 23:43:28
		01 Mar 2021 23:11:13
User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized nor that this was an important medical event. There is no copy of request for medical records. The AE SD log does not list an AE the event for the dates listed below.' (Site from CRA). Query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' canceled (Site from CRA). User opened query 'There is no documentation present in the source documents to confirm that the subject was hospitalized. There is no copy of request for medical records. The criteria SD section for "Important Medical Event" = No. Please update as appropriate. ' (Site from CRA). User closed query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).		01 Mar 2021 23:06:38
		01 Mar 2021 23:03:28
		01 Mar 2021 23:03:28

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' answered with 'corrected ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:51:49
User entered 'Yes (Y)'	System	22 Feb 2021 18:51:41
Un-reviewed for Safety.	Jill York (b) (4)	22 Feb 2021 18:51:41
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 18:51:41
User opened query 'There is no notation of hospitalization located in the SD for this event. Please confirm. Also please request hospital records if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:23:27
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Yes (Y)'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:43:11
DataPoint Un-verified.		01 Mar 2021 23:18:46
DataPoint Verified.		01 Mar 2021 22:47:04
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:57:37
DataPoint Un-verified.		01 Mar 2021 23:18:49
DataPoint Verified.		01 Mar 2021 22:47:07
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User closed query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).		29 Apr 2021 23:57:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:17:38
Query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' answered with 'Have tried to change multiple times, reverts back to original response.' (Site from CRA).	Shelby Pickle (b) (4)	09 Mar 2021 18:20:58
User entered 'No (N)'	System	09 Mar 2021 18:20:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:20:10
User entered 'No (N)'	System	09 Mar 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:19:29
User entered 'No (N)'	System	09 Mar 2021 18:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:17:04
User entered 'No (N)'	System	09 Mar 2021 18:16:39
Un-reviewed for Safety.	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	09 Mar 2021 18:16:39
User opened query 'Based on discussion with PI, this is "Yes". If agreed please update the SD and this response.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:00:21
DataPoint Un-verified.		03 Mar 2021 21:57:35
DataPoint Verified.		01 Mar 2021 23:43:09
DataPoint Un-verified.		01 Mar 2021 23:18:50
DataPoint Verified.		01 Mar 2021 22:47:11
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'No (N)'	System	22 Jan 2021 17:56:42

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:14
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Ripley'	System	22 Jan 2021 17:56:42

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:21
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Hollister'	System	22 Jan 2021 17:56:42

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:18
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 17:56:42

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Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:23
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'Colorado Springs'	System	22 Jan 2021 17:56:42



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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:17:38
DataPoint Verified.		01 Mar 2021 22:47:28
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:51:41

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:30
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered '80920'	System	22 Jan 2021 17:56:42

US3142236

Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:47:35
Reviewed for Safety.		22 Jan 2021 17:57:00
User entered 'US'	System	22 Jan 2021 17:56:55

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 12:18:23
User entered '3'	System	10 Mar 2021 14:18:11
User entered '2'	System	29 Jan 2021 15:11:43
User entered '1'	System	22 Jan 2021 17:56:55

**US3142236**

**Folder: SAE USA-US064-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:29:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered '02/Apr/2021 08:18'	(b) (4) System	02 Apr 2021 12:18:23

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Folder: SAE USA-US064-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

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**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)	29 Apr 2021 23:58:51
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:37:06
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 12:18:23