

US3142100 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:02:03

All time stamps listed in this document are displayed in GMT

**US3142100**

**Form: Participant Creation**

**Data signed:** (b) (4) 18 Apr 2021 19:39:26

**Generated On:** 11 Aug 2021 22:02:03

---

[Participant ID](#)

US3142100

---

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

---

---

US3142100

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3142100

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3142100

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Date of Informed Consent ( <i>dd MMM yyyy</i> )	4 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

US3142100

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3142100

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3142100

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	NEARSIGHTED BILATERAL
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	
Stop Year (derived)	



US3142100

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	CORRECTIVE LENS WEARER
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	
Stop Year (derived)	

US3142100

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1957
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1957
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1957
Start Year (derived)	1957
Stop Month and Year (derived)	JAN 1957
Stop Year (derived)	1957

US3142100

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN MAR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142100

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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



US3142100

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1967
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1967
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	JAN 1967
Stop Year (derived)	1967

US3142100

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	HYPERTENSION
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)	_____

US3142100

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Condition	INTERMITTENT HERPES SIMPLEX (COLD SORES)
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142100

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:21 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 15:21
Height ( <i>xxx.x</i> )	74 in
Weight ( <i>xxx.x</i> )	254.3 lb
BMI ( <i>xxx.x</i> )	32.71846 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)	

US3142100

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

US3142100

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

---

**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 ☐

---

**Specify**

REGULAR USE OF PUBLIC GYM

---

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

**No Risk Identified** True

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



US3142100

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

<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>	

US3142100

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184740

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 ☐

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 18 Apr 2021 19:39:50

**Generated On: 11 Aug 2021 22:02:03**

Height	ND - Not Done
Weight	ND - Not Done

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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)	04 AUG 2020
Time of assessment (00:00-23:59)	15:21 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:21
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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)	04 AUG 2020
Time of assessment (00:00-23:59)	17:04 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 17:04
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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.*

US3142100

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 16:34 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 16:34

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



US3142100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 AUG 2020

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

04 AUG 2020 13:00

US3142100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:39	04 AUG 2020 15:39
Nasopharyngeal Swab 2	Yes	15:39	04 AUG 2020 15:39

US3142100

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**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

98.0 °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

04 AUG 2020 17:08

PC Open Date & Time

04 AUG 2020 16:54

PC Close Date & Time

04 AUG 2020 19:24

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 04 AUG 2020 20:31

PC Open Date & Time 04 AUG 2020 20:19

PC Close Date & Time 05 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 14:31

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

**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

06 AUG 2020 18:11

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

---

**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

97.2 °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

07 AUG 2020 12:54

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59



US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**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

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

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:02:03

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

10 AUG 2020 10:50

---

PC Open Date & Time

09 AUG 2020 12:00

---

PC Close Date & Time

10 AUG 2020 11:59

---

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 12:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**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

04 AUG 2020 17:09

PC Open Date & Time

04 AUG 2020 16:54

PC Close Date & Time

04 AUG 2020 19:24

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**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

04 AUG 2020 20:32

PC Open Date & Time

04 AUG 2020 20:19

PC Close Date & Time

05 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 14:31

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

**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

06 AUG 2020 18:10

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

**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

07 AUG 2020 12:47

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59



US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

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

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

**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

10 AUG 2020 09:34

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**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

10 AUG 2020 12:55

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 17:09
PC Open Date & Time	04 AUG 2020 16:54
PC Close Date & Time	04 AUG 2020 19:24

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:33
PC Open Date & Time	04 AUG 2020 20:19
PC Close Date & Time	05 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2821

EAB) (1725)



US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:02:03

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 14:32
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2821

EAB) (1725)

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:02:03

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:11
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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 ☒

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:47
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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)

61 of 2821

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Yes ☐

PC Time stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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 ☒



US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 09:35
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

65 of 2821

EAB) (1725)

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 12:55
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3142100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3142100

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:15
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	12:42 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 12:42
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3142100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 SEP 2020

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

Treatment Date and Time (derived) 03 SEP 2020 12:12

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

What was the frequency of the study treatment dosing? ONCE

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

US3142100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 SEP 2020

Collection time (00:00-23:59)

11:36 (24 HR)

Collection date and time (derived)

3 SEP 2020 11:36

US3142100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	3 SEP 2020 11:30
Nasopharyngeal Swab 2	Yes	11:30	3 SEP 2020 11:30



US3142100

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:32

PC Close Date & Time

03 SEP 2020 15:02

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 03 SEP 2020 15:57

PC Close Date & Time 04 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 08:10

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:31

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**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

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:02:03

**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

08 SEP 2020 15:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 07:48

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:32

PC Close Date & Time

03 SEP 2020 15:02

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 15:57

PC Close Date & Time

04 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 08:10

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 18:29

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 19:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

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

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

**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

08 SEP 2020 15:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**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

10 SEP 2020 07:48

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 12:32

PC Close Date & Time

03 SEP 2020 15:02

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**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 ☐

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 15:57

PC Close Date & Time

04 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**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 ☒

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

		Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 08:11	
PC Open Date & Time	04 SEP 2020 12:00	
PC Close Date & Time	05 SEP 2020 11:59	

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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 ☒



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:30
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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 ☒

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**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)

107 of 2821

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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 ☒

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

111 of 2821

EAB) (1725)



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 07:49
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3142100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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*

US3142100

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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



US3142100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 13:59
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142100

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3142100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

14:12 (24 HR)

Collection date and time (derived)

20 OCT 2020 14:12

US3142100

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 OCT 2020 15:23:41
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 OCT 2020 15:13:30
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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

21 OCT 2020 18:07:16

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 17:00:43

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59



US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 15:04:20

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3142100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 20:20:32
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:39:00
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 22:13:28

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 13:48:47
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 11:29:52

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 DEC 2020 13:23:19
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 18:06:41
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 11:59:50

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 16:01:56

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 17:06:11

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 09:24:42

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 15:56:06

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 17:59:53

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 14:04:06

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 FEB 2021 10:26:40
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 20:38:32

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 12:51:47

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 MAR 2021 17:04:17
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 21:22:40

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

Date and time of submission

25 MAR 2021 09:50:33

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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

01 APR 2021 09:16:02

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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

08 APR 2021 15:31:15

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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

15 APR 2021 10:30:13

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 09:17:56

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 18:00:11

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

06 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAY 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAY 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
---	-------------------

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 SEP 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 SEP 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 OCT 2021 23:59

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 NOV 2021 23:59

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 NOV 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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°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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

30 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 JAN 2022 23:59

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 JAN 2022 23:59

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 MAR 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 APR 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 APR 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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°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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 MAY 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAY 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 JUN 2022 23:59

---



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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°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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 JUN 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 JUL 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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°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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 SEP 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59



US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

---

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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 <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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

**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 ☐

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3142100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:03

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"/>

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59



**US3142100**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 11 Aug 2021 22:02:03**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 20:38:51

US3142100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3142100

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT4

US3142100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

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) \_\_\_\_\_

US3142100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3142100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 FEB 2021

Collection time (00:00-23:59)

14:24 (24 HR)

Collection date and time (derived)

11 FEB 2021 14:24

US3142100

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:50

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3142100

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3142100**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

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*

**US3142100**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Date of Contact	23 SEP 2020
Time of Contact	12:30
Date and Time of Contact (derived)	23 SEP 2020 12:30
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.9 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

324 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101 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 type="radio"/>
	Moderate	<input checked="" 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)

328 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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)

329 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	24 SEP 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.2 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)

332 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.3 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)

336 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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)

337 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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)

340 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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)

341 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	27 SEP 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

345 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.0 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 type="radio"/>
	Moderate	<input checked="" 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)

348 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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)

349 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.6 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	100.9 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

357 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 type="checkbox"/>
Day 12	<input checked="" 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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	102.3 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)

360 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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)

361 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	101.4 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

364 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

365 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	04 OCT 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	05 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	90 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	101.0 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)

372 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 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 checked="" 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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	101.2 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 type="radio"/>
	Moderate	<input checked="" 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)

376 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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)

377 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 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 checked="" 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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.8 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)

380 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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 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)

381 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	21 SEP 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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	22 SEP 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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"/>

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Date of Visit	23 SEP 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	23 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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)	1



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:39:22

Generated On: 11 Aug 2021 22:02:03

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 01 OCT 2020

End Date 14 OCT 2020

Oxygen Saturation 90 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 2821

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:39:22

Generated On: 11 Aug 2021 22:02:03

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:39:22

Generated On: 11 Aug 2021 22:02:03

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 26 Apr 2021 02:39:22

**Generated On: 11 Aug 2021 22:02:03**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 OCT 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	20 OCT 2020

US3142100

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	SICKD1

US3142100

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:32
Height (xxx.x)	74 in
Weight (xxx.x)	256.1 lb
Temperature (xxx.x)	98.9 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142100

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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



US3142100

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 19:39:27

Generated On: 11 Aug 2021 22:02:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 SEP 2020

US3142100

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	SICKD28

US3142100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 13:59
Height (xxx.x)	74 in
Weight (xxx.x)	146.4 lb
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142100

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3142100

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 OCT 2020

US3142100

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

Visit date (dd MMM yyyy)	11 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	UNBLND_DECIDE
------------	---------------

US3142100

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 FEB 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> )	11 FEB 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

**US3142100**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 18 Apr 2021 19:39:49

**Generated On: 11 Aug 2021 22:02:03**

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



US3142100

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	13:52 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 13:52
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:06
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3142100

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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) 11 FEB 2021

What was the treatment time? (00:00-23:59) 14:36 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 14:36

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

US3142100

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 FEB 2021

Collection time (00:00-23:59)

14:24 (24 HR)

Collection date and time (derived)

11 FEB 2021 14:24

US3142100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	14:24
---------------------------------	-------

Collection Date and Time (derived)	11 FEB 2021 14:24
------------------------------------	-------------------

US3142100

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3142100

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3142100

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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)	9 MAR 2021
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 14:19
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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)	9 MAR 2021
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 15:09
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3142100

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3142100

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

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) 9 MAR 2021

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 14:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3142100

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:39:27

Generated On: 11 Aug 2021 22:02:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 18 Apr 2021 19:39:49

**Generated On: 11 Aug 2021 22:02:03**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Data signed:** (b) (4) 18 Apr 2021 19:39:49

**Generated On: 11 Aug 2021 22:02:03**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142100

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3142100

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 14:15
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142100

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

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.*

US3142100

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	29 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:21 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	29 MAR 2021 14:21
------------------------------------	-------------------

US3142100

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

AEID	USA-US064-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

430 of 2821

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	



US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

---

PATIENT BEGAN HAVING MILD SYMPTOMS LATE IN THE DAY ON 21SEP2020, AFTER A SPOUSE HAD RECEIVED A POSITIVE COVID-19 TEST FROM ANOTHER FACILITY. THE PATIENT WAS SEEN ONSITE FOR COVID-19 CONFIRMATION TESTING ON 23SEP2020. THE PATIENT TESTED POSITIVE AT THIS VISIT. THE PATIENT'S SYMPTOMS ARE BEING CLOSELY MONITORED BY THE CRC AND PI FOR ANY SIGNIFICANT CHANGES, SUCH AS WORSENING OR RECOVERY. PATIENT DID NOT VISIT ANY OTHER MEDICAL FACILITY OUTSIDE OF THE RESEARCH SITE. THE PATIENT DID USE MOTRIN/ TYLENOL INTERMITTENTLY FOR FEVER REDUCTION PURPOSES.

---

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

---

---

US3142100

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

AEID

Adverse event

ALOPECIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

433 of 2821

EAB) (1725)

US3142100

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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	PATIENT EXPERIENCED MILD BUT NOTICEABLE ALOPECIA POST COVID-19 DIAGNOSIS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

---

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

Yes ☒

No ☐

---

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

---

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

436 of 2821

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	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"/>

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

438 of 2821

EAB) (1725)

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

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



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐  
No ☒

Indication GOUT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

440 of 2821

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication RESTASIS EYE DROPS

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC DRY EYE

Dose per administration 2

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

If dose unit is Other, specify DROPS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

442 of 2821

EAB) (1725)

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

444 of 2821

EAB) (1725)

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

446 of 2821

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	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 2010	
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"/>



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication MOTRIN

Prophylaxis Yes ☐  
No ☒

Indication FEVER REDUCTION - COVID 19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

448 of 2821

EAB) (1725)

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	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)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER REDUCTION - COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

450 of 2821

EAB) (1725)

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

	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)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3142100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 19:39:26

Generated On: 11 Aug 2021 22:02:03

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3142100

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:02:03

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

US3142100

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:02:03

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 ☐

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6



US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	30/SEP/2020 16:11
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

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:32
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

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	20/OCT/2020 20:40
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

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	23/OCT/2020 22:08
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

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 14:43
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

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 18 Apr 2021 19:39:49

Generated On: 11 Aug 2021 22:02:03

SAEID	USA-US064-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	6
Date of submission (Pre-filled from custom function)	07/JAN/2021 19:45
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

US3142100 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

**US3142100**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:02:03**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 15:19:30
User entered 'US3142100'	(b) (4), (b) (6)	
	RWS_ENDPOINT	04 Aug 2020 20:59:17
	ENDPOINT (b) (4)	



**US3142100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:31:54
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:37:34

**US3142100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	27 Oct 2020 15:31:57
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:59:18

**US3142100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:31:58
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	04 Aug 2020 22:37:34

**US3142100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'SCRN'	System	04 Aug 2020 22:37:34

US3142100

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	27 Oct 2020 15:42:49
User entered '(b) (6) 1951'	(b) (4), (b) (6)	04 Aug 2020 20:59:19
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:42:52
User entered '69'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'YEARS'	System	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '69'	System	04 Aug 2020 22:39:27



**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	27 Oct 2020 15:42:57
User entered 'Male (M)'	Meghan York (b) (4)	04 Aug 2020 22:38:29
	(b) (4)	

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:43:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:26
User entered 'l'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:28
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:30
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29



**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:02:03**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:45:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:38:29

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:02:09
User entered '4 Aug 2020'	Meghan York (b) (4)	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Aug 2020'	System	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2020'	System	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
DataPoint Verified.		27 Apr 2021 23:34:01
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Un-verified.	(b) (4)	
	Meghan York (b) (4)	09 Dec 2020 23:08:31
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Meghan York (b) (4)	09 Dec 2020 23:08:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:02:24
User entered 'Amendment 1 (1)'	Meghan York (b) (4)	04 Aug 2020 22:39:27
	(b) (4)	

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:02:29
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:39:27



**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:02:26
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:02:30
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:02:37
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:39:27

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	27 Oct 2020 16:02:39
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:59:18
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

**US3142100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:02:03**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'I'	System	04 Aug 2020 22:39:31

**US3142100**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:02:03**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:03:34
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:39:31

**US3142100**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:02:03**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:03:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4)	05 Aug 2020 18:50:46
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:45:28

US3142100

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:09:31
User closed query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' (Site from DM).		19 Oct 2020 16:53:57
Query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' answered with 'Subject is not taking any medications for this condition. Not considered an AE' (Site from DM).	Meghan York (b) (4) (b) (4)	13 Oct 2020 17:08:54
User opened query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:35:47
User closed query 'Per DM CLR: Please specify the location of NEARSIGHTED (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		13 Oct 2020 03:35:23
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	(b) (4) (b) (4)	09 Oct 2020 18:11:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:11:25
Data point term sent to Coder	System	09 Oct 2020 18:10:44
Query 'Per DM CLR: Please specify the location of NEARSIGHTED (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	09 Oct 2020 18:10:21
Coding entries removed.	Meghan York (b) (4) (b) (4)	09 Oct 2020 18:10:15



US3142100

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
User entered 'NEARSIGHTED bilateral' reason for change: Data Entry Error	Meghan York (b) (4)	09 Oct 2020 18:10:15
User opened query 'Per DM CLR: Please specify the location of NEARSIGHTED (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:02:51
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)	08 Aug 2020 20:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:14:47
Data point term sent to Coder	System	08 Aug 2020 20:13:48
User entered 'Nearsighted'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:07:26
User entered 'UN UNK 1962'	Shelby Pickle (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:07:29
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:07:34
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:07:39
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:07:41
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1962'	System	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1962'	System	08 Aug 2020 20:12:57



**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:12:57

**US3142100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:12:57

US3142100

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:08:57
User closed query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' (Site from DM).		19 Oct 2020 16:54:04
Query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' answered with 'Subject is not taking any medications for this condition. Not considered an AE' (Site from DM).	Meghan York (b) (4) (b) (4)	13 Oct 2020 17:09:12
User opened query 'Per CDM: Response noted. Please update the MHx condition with any corresponding AE or ConMed entries, if applicable. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:35:57
User closed query 'Per DM CLR: Please specify the location of ASTIGMATISM (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		13 Oct 2020 03:35:27
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	(b) (4) (b) (4)	09 Oct 2020 18:11:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	09 Oct 2020 18:11:24
Query 'Per DM CLR: Please specify the location of ASTIGMATISM (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	09 Oct 2020 18:10:47
Data point term sent to Coder	System	09 Oct 2020 18:10:44
Coding entries removed.	Meghan York (b) (4) (b) (4)	09 Oct 2020 18:10:40

US3142100

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
User entered 'ASTIGMATISM bilateral' reason for change: Data Entry Error	Meghan York (b) (4)	09 Oct 2020 18:10:40
User opened query 'Per DM CLR: Please specify the location of ASTIGMATISM (Left Eye, Right Eye, Bilateral ). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 03:03:06
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)	08 Aug 2020 20:14:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:14:46
Data point term sent to Coder	System	08 Aug 2020 20:13:48
User entered 'Astigmatism'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:00
DataPoint Un-verified.		27 Oct 2020 16:09:57
DataPoint Verified.		27 Oct 2020 16:09:00
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:19
	(b) (4)	

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:09:01
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:09:04
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:09:06
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:13:19



**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:09:09
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:13:19

**US3142100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:13:19

US3142100

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 15:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 20:13:48
User entered 'Chronic Dry Eyes'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47
	(b) (4)	

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2017'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47



**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2017'	System	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2017'	System	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:13:47

**US3142100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:13:47

US3142100

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Corrective lens wearer - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:15:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:15:47
Data point term sent to Coder	System	08 Aug 2020 20:14:51
User entered 'Corrective Lens Wearer'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09
	(b) (4)	



**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1962'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1962'	System	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1962'	System	08 Aug 2020 20:14:09

**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:14:09



**US3142100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:14:09

US3142100

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:15:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:15:47
Data point term sent to Coder	System	08 Aug 2020 20:14:49
User entered 'Tonsillitis'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1957'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'No (N)'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1957'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1957'	System	08 Aug 2020 20:14:34



**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1957'	System	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1957'	System	08 Aug 2020 20:14:34

**US3142100**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1957'	System	08 Aug 2020 20:14:34

US3142100

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Dental implantation, LLT: Dental implantation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:20
Data point term sent to Coder	System	08 Aug 2020 20:15:52
User entered 'Dental Implant'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN Apr 2020'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56



**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Apr 2020'	System	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2020'	System	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:14:56

**US3142100**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:14:56

US3142100

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:16:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:16:48
Data point term sent to Coder	System	08 Aug 2020 20:15:53
User entered 'Hypercholesterolemia'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16



**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:16

**US3142100**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:16

US3142100

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:16:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:16:48
Data point term sent to Coder	System	08 Aug 2020 20:15:52
User entered 'Vitamin D Deficiency'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43



**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN Mar 2019'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Mar 2019'	System	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2019'	System	08 Aug 2020 20:15:43

**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:43



**US3142100**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:43

US3142100

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:10:26
User closed query 'Per DM CLR: Please specify the location of GOUT, (e.g bilateral knee, right wrist etc) Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		13 Oct 2020 22:31:56
Query 'Per DM CLR: Please specify the location of GOUT, (e.g bilateral knee, right wrist etc) Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'location was not specified ' (Site from DM).	Meghan York (b) (4) (b) (4)	09 Oct 2020 18:11:12
User opened query 'Per DM CLR: Please specify the location of GOUT, (e.g bilateral knee, right wrist etc) Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 03:04:00
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:17:49
Data point term sent to Coder	System	08 Aug 2020 20:16:53
User entered 'Gout'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2017'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2017'	System	08 Aug 2020 20:15:57



**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2017'	System	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:57

**US3142100**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:15:57

US3142100

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:17:49
Data point term sent to Coder	System	08 Aug 2020 20:16:53
User entered 'Migraines'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1967'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'No (N)'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1967'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18



**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1967'	System	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1967'	System	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1967'	System	08 Aug 2020 20:16:18

**US3142100**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1967'	System	08 Aug 2020 20:16:18

US3142100

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:17:49
Data point term sent to Coder	System	08 Aug 2020 20:16:53
User entered 'Hypertension'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2015'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38



**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2015'	System	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2015'	System	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:16:38

**US3142100**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:16:38

US3142100

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
Data point term sent to Coder	System	08 Aug 2020 20:17:54
User entered 'Deep Vein Thrombosis'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08



**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'No (N)'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:17:08

**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:17:08



**US3142100**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:17:08

US3142100

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:02:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
Data point term sent to Coder	System	08 Aug 2020 20:17:54
User entered 'Pulmonary Embolism'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'No (N)'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 2018'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:17:26



**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 2018'	System	08 Aug 2020 20:17:26

**US3142100**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '2018'	System	08 Aug 2020 20:17:26

US3142100

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:02:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Cold sores - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:18:49
Data point term sent to Coder	System	08 Aug 2020 20:17:54
User entered 'Intermittent Herpes Simplex (Cold Sores)'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'UN UNK 1966'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered empty.	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48



**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:26
User entered '0'	Shelby Pickle (b) (4)	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'Jan 1966'	System	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '1966'	System	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered empty.	System	08 Aug 2020 20:17:48

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:01
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:04
User entered '4 Aug 2020'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:06
User entered '15:21'	Meghan York (b) (4)	04 Aug 2020 22:49:30



**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered '4 Aug 2020 15:21'	System	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:09
User entered '74' in	Meghan York (b) (4)	04 Aug 2020 22:49:30
DataPoint set to visible.	(b) (4) System	04 Aug 2020 22:39:31

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:13
User entered '254.3' lb	Meghan York (b) (4)	04 Aug 2020 22:49:30
DataPoint set to visible.	(b) (4) System	04 Aug 2020 22:39:31

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
Amendment Manager: User entered '32.71846'	System	16 Sep 2020 23:43:12
User entered '32.7'	System	04 Aug 2020 22:49:30
DataPoint set to visible.	System	04 Aug 2020 22:39:31

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'kg/m2'	System	04 Aug 2020 22:49:30
DataPoint set to visible.	System	04 Aug 2020 22:39:31

US3142100

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:11:16
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).		28 Sep 2020 02:36:21
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:17:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:45:34
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:36:53
User entered '96.8' F	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:23
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered 'Other (Other)'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:40
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered 'temporal'	Meghan York (b) (4)	04 Aug 2020 22:49:30



**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered '99'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'bpm'	System	04 Aug 2020 22:49:30

US3142100

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered '16'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'breaths/min'	System	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered '124'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'mmHg'	System	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:34
User entered '75'	Meghan York (b) (4)	04 Aug 2020 22:49:30

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User entered 'mmHg'	System	04 Aug 2020 22:49:30



**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26

**US3142100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26

**US3142100**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:08
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:49:37

US3142100

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:12:10
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		30 Sep 2020 21:12:07
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 19:12:16
User entered '4 Aug 2020'	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:49:37

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:37
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:40
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:47
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:49
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40



US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:52
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:57
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:59
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:02
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:05
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:08
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:10
User entered 'No (N)'	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:16
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:50:40



US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:21
User entered 'regular use of public gym'	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'I'	(b) (4) Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:31
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:34
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:36
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:50:40

US3142100

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:03

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:38
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:40
User entered '0'	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '0'	(b) (4) Meghan York (b) (4)	04 Aug 2020 22:50:40



**US3142100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:25:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:47
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:50:40

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:50:52

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:40
User entered '4 Aug 2020'	Meghan York (b) (4)	04 Aug 2020 22:50:52

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:43
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	04 Aug 2020 22:50:52

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'VISIT1'	System	04 Aug 2020 22:50:52

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:46
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 22:29:17

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:15:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:06:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:06:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 22:29:17
User entered '184740' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 22:29:17

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:02:03**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	27 Oct 2020 16:15:53
User entered '>=65 years (3)'	(b) (4), (b) (6)	
	RWS_ENDPOINT	04 Aug 2020 22:29:17
	ENDPOINT (b) (4)	



US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:16:52
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 22:54:55
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	04 Aug 2020 22:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:53:35
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:53:35

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:16:53
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 22:54:55
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	04 Aug 2020 22:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:53:35
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:53:35

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:16:55
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 22:54:55
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:53:35
User entered empty.	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:53:35

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:16:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 22:54:55
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:53:35
User entered empty.	Meghan York (b) (4) (b) (4)	04 Aug 2020 22:53:35

US3142100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:54:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 22:54:55
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	04 Aug 2020 22:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 22:53:35
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:53:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:02:03**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
DataPoint set to visible.	System	09 Dec 2020 23:08:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 03:40:06

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:17:13
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:45:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:17:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:45:48
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 07:54:26
User entered '74' in	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:17:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:48
User entered '254.3' lb	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35



US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:17:13
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:45:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:17:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:45:48
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 07:54:26
User entered '74' in	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:17:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:48
User entered '254.3' lb	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Aug 2020 20:19:52
User entered '04 Aug 2020' reason for change: Data Entry Error	System	08 Aug 2020 20:19:52
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35
User entered '07 Aug 2020'	(b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	08 Aug 2020 20:19:52
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	08 Aug 2020 20:19:35
User entered '15:21'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35
	(b) (4)	

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '04 Aug 2020 15:21'	System	08 Aug 2020 20:19:52
User entered '07 Aug 2020 15:21'	System	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '96.8' F	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35



**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '99'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'bpm'	System	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '16'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'breaths/min'	System	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '124'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	08 Aug 2020 20:19:35



US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '75'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:17:13
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 16:45:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 18:17:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 19:45:48
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 07:54:26
User entered '74' in	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:17:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 19:45:48
User entered '254.3' lb	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Aug 2020 20:20:08
User entered '04 Aug 2020' reason for change: Data Entry Error	System	08 Aug 2020 20:20:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35
User entered '07 Aug 2020'	(b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 12:50:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol 30 minute observation period' (Site from System).	Shelby Pickle (b) (4)	08 Aug 2020 20:20:20
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).		08 Aug 2020 20:20:08
User entered '17:04'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35



**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '04 Aug 2020 17:04'	System	08 Aug 2020 20:20:08
User entered '07 Aug 2020 17:04'	System	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '98.0' F	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

US3142100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Temporal'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '66'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'bpm'	System	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '18'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'breaths/min'	System	08 Aug 2020 20:19:35



**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '144'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '92'	Shelby Pickle (b) (4)	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	08 Aug 2020 20:19:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:18:08
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:17:32
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:20:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:18:11
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	25 Sep 2020 18:17:32
User entered '04 Aug 2020'	Shelby Pickle (b) (4)	08 Aug 2020 20:20:35

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:21:38
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:21:40
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:39:59



US3142100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:21:46
User entered empty.	Meghan York (b) (4)	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:22:37
User entered '4 Aug 2020'	Meghan York (b) (4)	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:22:40
User entered '16:34'	Meghan York (b) (4)	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '4 Aug 2020 16:34'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:22:53
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
DataPoint Verified.		27 Oct 2020 16:22:57
User entered 'ONCE'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:23:53
User entered 'Yes (Y)'		05 Aug 2020 21:59:10

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:23:55
User entered '04 Aug 2020'		05 Aug 2020 21:59:10

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:23:57
User entered '13:00'		05 Aug 2020 21:59:10

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '04 Aug 2020 13:00'	System	05 Aug 2020 21:59:10

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:24:12
User entered '04 Aug 2020'	Shelby Pickle (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '15:39'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:20:54



**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered '04 Aug 2020 15:39'	System	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '15:39'	(b) (4) Shelby Pickle (b) (4)	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered '04 Aug 2020 15:39'	System	08 Aug 2020 20:20:54

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:42
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	08 Aug 2020 20:21:00

**US3142100**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered '1'	System	08 Aug 2020 20:21:00

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T16:58:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9c9e8f73-d567-472b-b8be-89a5450dbb05' User entered 'Yes (Y)'	System	04 Aug 2020 23:08:18
	System	04 Aug 2020 23:08:18

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:07:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9c9e8f73-d567-472b-b8be-89a5450dbb05' User entered '98.0'	System	04 Aug 2020 23:08:18
	System	04 Aug 2020 23:08:18

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:07:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9c9e8f73-d567-472b-b8be-89a5450dbb05'	System	04 Aug 2020 23:08:18
User entered 'No (N)'	System	04 Aug 2020 23:08:18

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:08:16', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9c9e8f73-d567-472b-b8be-89a5450dbb05' User entered '04 Aug 2020 17:08'	System	04 Aug 2020 23:08:18
	System	04 Aug 2020 23:08:18

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 16:54'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 19:24'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:30:26', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9aa3c8ad-9b6c-47fd-9e82-f88f589d5163' User entered 'Yes (Y)'	System	05 Aug 2020 02:31:37
	System	05 Aug 2020 02:31:37



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:31:13', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9aa3c8ad-9b6c-47fd-9e82-f88f589d5163' User entered '98.4'	System	05 Aug 2020 02:31:37
	System	05 Aug 2020 02:31:37

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:31:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9aa3c8ad-9b6c-47fd-9e82-f88f589d5163'	System	05 Aug 2020 02:31:37
User entered 'No (N)'	System	05 Aug 2020 02:31:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:31:36', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9aa3c8ad-9b6c-47fd-9e82-f88f589d5163' User entered '04 Aug 2020 20:31'	System	05 Aug 2020 02:31:37
	System	05 Aug 2020 02:31:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 20:19'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 2'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07092094-34b8-4352-bade-f6eefe7ec58e' User entered 'Yes (Y)'	System	05 Aug 2020 20:31:27
	System	05 Aug 2020 20:31:27

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07092094-34b8-4352-bade-f6eefe7ec58e' User entered '97.4'	System	05 Aug 2020 20:31:27
	System	05 Aug 2020 20:31:27



US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:20', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07092094-34b8-4352-bade-f6eefe7ec58e'	System	05 Aug 2020 20:31:27
User entered 'No (N)'	System	05 Aug 2020 20:31:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:24', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07092094-34b8-4352-bade-f6eefe7ec58e' User entered '05 Aug 2020 14:31'	System	05 Aug 2020 20:31:27
	System	05 Aug 2020 20:31:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 3'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ed34bcc1-ced7-4fd7-8d14-d64c26874dc3' User entered 'Yes (Y)'	System	07 Aug 2020 00:11:58
	System	07 Aug 2020 00:11:58

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ed34bcc1-ced7-4fd7-8d14-d64c26874dc3' User entered '97.9'	System	07 Aug 2020 00:11:58
	System	07 Aug 2020 00:11:58

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:53', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ed34bcc1-ced7-4fd7-8d14-d64c26874dc3' User entered 'No (N)'	System	07 Aug 2020 00:11:58
	System	07 Aug 2020 00:11:58



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:57', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ed34bcc1-ced7-4fd7-8d14-d64c26874dc3' User entered '06 Aug 2020 18:11'	System	07 Aug 2020 00:11:58
	System	07 Aug 2020 00:11:58

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 4'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:50:56', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ead5a945-b198-475d-b5e3-b3fc23cbb765' User entered 'Yes (Y)'	System	07 Aug 2020 18:54:15
	System	07 Aug 2020 18:54:15

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:53:57', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ead5a945-b198-475d-b5e3-b3fc23cbb765' User entered '97.2'	System	07 Aug 2020 18:54:15
	System	07 Aug 2020 18:54:15

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:54:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ead5a945-b198-475d-b5e3-b3fc23cbb765'	System	07 Aug 2020 18:54:15
User entered 'No (N)'	System	07 Aug 2020 18:54:15

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:54:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ead5a945-b198-475d-b5e3-b3fc23cbb765' User entered '07 Aug 2020 12:54'	System	07 Aug 2020 18:54:15
	System	07 Aug 2020 18:54:15



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 5'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 6'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T10:49:49', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '340e99af-07f4-409c-8015-4d99e2cdb36d' User entered 'Yes (Y)'	System	10 Aug 2020 16:50:09
	System	10 Aug 2020 16:50:09

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T10:49:58', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '340e99af-07f4-409c-8015-4d99e2cdb36d' User entered '97.6'	System	10 Aug 2020 16:50:09
	System	10 Aug 2020 16:50:09

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T10:50:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '340e99af-07f4-409c-8015-4d99e2cdb36d' User entered 'No (N)'	System	10 Aug 2020 16:50:09
	System	10 Aug 2020 16:50:09

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T10:50:07', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '340e99af-07f4-409c-8015-4d99e2cdb36d' User entered '10 Aug 2020 10:50'	System	10 Aug 2020 16:50:09
	System	10 Aug 2020 16:50:09



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 7'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:54:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd09b6f22-3469-48d6-825c-447af7a9e530'	System	10 Aug 2020 18:55:04
User entered 'Yes (Y)'	System	10 Aug 2020 18:55:04

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:54:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd09b6f22-3469-48d6-825c-447af7a9e530' User entered '97.7'	System	10 Aug 2020 18:55:04
	System	10 Aug 2020 18:55:04

US3142100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:54:58', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd09b6f22-3469-48d6-825c-447af7a9e530'	System	10 Aug 2020 18:55:04
User entered 'No (N)'	System	10 Aug 2020 18:55:04

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd09b6f22-3469-48d6-825c-447af7a9e530'	System	10 Aug 2020 18:55:04
User entered '10 Aug 2020 12:55'	System	10 Aug 2020 18:55:04

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:08:27', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '68c0a052-1cdf-44d3-bec2-56aa65ae9822'	System	04 Aug 2020 23:09:03
User entered 'None (1)'	System	04 Aug 2020 23:09:03

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:08:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '68c0a052-1cdf-44d3-bec2-56aa65ae9822'	System	04 Aug 2020 23:09:03
User entered 'No (N)'	System	04 Aug 2020 23:09:03

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:08:51', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '68c0a052-1cdf-44d3-bec2-56aa65ae9822'	System	04 Aug 2020 23:09:03
User entered 'No (N)'	System	04 Aug 2020 23:09:03

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:08:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '68c0a052-1cdf-44d3-bec2-56aa65ae9822'	System	04 Aug 2020 23:09:03
User entered 'None (1)'	System	04 Aug 2020 23:09:03

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '68c0a052-1cdf-44d3-bec2-56aa65ae9822' User entered '04 Aug 2020 17:09'	System	04 Aug 2020 23:09:03
	System	04 Aug 2020 23:09:03

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 16:54'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 19:24'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:31:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a06a591f-32ee-4530-ad8e-9c23e83b4e31' User entered 'None (1)'	System	05 Aug 2020 02:32:37
	System	05 Aug 2020 02:32:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:31:58', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a06a591f-32ee-4530-ad8e-9c23e83b4e31' User entered 'No (N)'	System	05 Aug 2020 02:32:37
	System	05 Aug 2020 02:32:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a06a591f-32ee-4530-ad8e-9c23e83b4e31' User entered 'No (N)'	System	05 Aug 2020 02:32:37
	System	05 Aug 2020 02:32:37

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:18', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a06a591f-32ee-4530-ad8e-9c23e83b4e31' User entered 'None (1)'	System	05 Aug 2020 02:32:37
	System	05 Aug 2020 02:32:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:34', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a06a591f-32ee-4530-ad8e-9c23e83b4e31' User entered '04 Aug 2020 20:32'	System	05 Aug 2020 02:32:37
	System	05 Aug 2020 02:32:37

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 20:19'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 2'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07b78189-96ab-4fc8-8cee-7b34533c4577'	System	05 Aug 2020 20:31:44
User entered 'None (1)'	System	05 Aug 2020 20:31:44

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:32', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07b78189-96ab-4fc8-8cee-7b34533c4577'	System	05 Aug 2020 20:31:44
User entered 'No (N)'	System	05 Aug 2020 20:31:44

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:35', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07b78189-96ab-4fc8-8cee-7b34533c4577'	System	05 Aug 2020 20:31:44
User entered 'No (N)'	System	05 Aug 2020 20:31:44

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:39', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07b78189-96ab-4fc8-8cee-7b34533c4577'	System	05 Aug 2020 20:31:44
User entered 'None (1)'	System	05 Aug 2020 20:31:44

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:42', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '07b78189-96ab-4fc8-8cee-7b34533c4577'	System	05 Aug 2020 20:31:44
User entered '05 Aug 2020 14:31'	System	05 Aug 2020 20:31:44

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 3'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:09:59', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '001fbc32-1f5b-4d2b-b846-69100e5c0106'	System	07 Aug 2020 00:10:15
User entered 'None (1)'	System	07 Aug 2020 00:10:15

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:03', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '001fbc32-1f5b-4d2b-b846-69100e5c0106'	System	07 Aug 2020 00:10:15
User entered 'No (N)'	System	07 Aug 2020 00:10:15

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '001fbc32-1f5b-4d2b-b846-69100e5c0106' User entered 'No (N)'	System	07 Aug 2020 00:10:15
	System	07 Aug 2020 00:10:15

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:08', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '001fbc32-1f5b-4d2b-b846-69100e5c0106'	System	07 Aug 2020 00:10:15
User entered 'None (1)'	System	07 Aug 2020 00:10:15

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '001fbc32-1f5b-4d2b-b846-69100e5c0106' User entered '06 Aug 2020 18:10'	System	07 Aug 2020 00:10:15
	System	07 Aug 2020 00:10:15

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 4'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:46:49', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e4637fd-d956-4e04-8cc1-5178d7757971' User entered 'None (1)'	System	07 Aug 2020 18:47:11
	System	07 Aug 2020 18:47:11

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:46:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e4637fd-d956-4e04-8cc1-5178d7757971' User entered 'No (N)'	System	07 Aug 2020 18:47:11
	System	07 Aug 2020 18:47:11

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:46:56', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e4637fd-d956-4e04-8cc1-5178d7757971' User entered 'No (N)'	System	07 Aug 2020 18:47:11
	System	07 Aug 2020 18:47:11

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e4637fd-d956-4e04-8cc1-5178d7757971' User entered 'None (1)'	System	07 Aug 2020 18:47:11
	System	07 Aug 2020 18:47:11

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:08', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e4637fd-d956-4e04-8cc1-5178d7757971' User entered '07 Aug 2020 12:47'	System	07 Aug 2020 18:47:11
	System	07 Aug 2020 18:47:11

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 5'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 6'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:09', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8bf23558-0f5a-4b90-a235-cc371ab630fb' User entered 'None (1)'	System	10 Aug 2020 15:34:31
	System	10 Aug 2020 15:34:31

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:13', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8bf23558-0f5a-4b90-a235-cc371ab630fb' User entered 'No (N)'	System	10 Aug 2020 15:34:31
	System	10 Aug 2020 15:34:31

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8bf23558-0f5a-4b90-a235-cc371ab630fb' User entered 'No (N)'	System	10 Aug 2020 15:34:31
	System	10 Aug 2020 15:34:31

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:23', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8bf23558-0f5a-4b90-a235-cc371ab630fb' User entered 'None (1)'	System	10 Aug 2020 15:34:31
	System	10 Aug 2020 15:34:31



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:27', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8bf23558-0f5a-4b90-a235-cc371ab630fb' User entered '10 Aug 2020 09:34'	System	10 Aug 2020 15:34:31
	System	10 Aug 2020 15:34:31

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 7'	System	04 Aug 2020 22:39:59

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:05', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '5ea32ac2-47d4-4934-8168-2561605a5749' User entered 'None (1)'	System	10 Aug 2020 18:55:19
	System	10 Aug 2020 18:55:19

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:09', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '5ea32ac2-47d4-4934-8168-2561605a5749' User entered 'No (N)'	System	10 Aug 2020 18:55:19
	System	10 Aug 2020 18:55:19

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:11', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '5ea32ac2-47d4-4934-8168-2561605a5749' User entered 'No (N)'	System	10 Aug 2020 18:55:19
	System	10 Aug 2020 18:55:19

US3142100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '5ea32ac2-47d4-4934-8168-2561605a5749' User entered 'None (1)'	System	10 Aug 2020 18:55:19
	System	10 Aug 2020 18:55:19



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '5ea32ac2-47d4-4934-8168-2561605a5749' User entered '10 Aug 2020 12:55'	System	10 Aug 2020 18:55:19
	System	10 Aug 2020 18:55:19

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:10', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:20', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:27', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:29', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:31', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered 'None (0)'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48'	System	04 Aug 2020 23:09:52
User entered 'No (N)'	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T17:09:49', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e663cf31-a7b6-4d0f-876c-ec202ea6dd48' User entered '04 Aug 2020 17:09'	System	04 Aug 2020 23:09:52
	System	04 Aug 2020 23:09:52

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 16:54'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 19:24'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:39', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:42', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:51', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'None (0)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:32:59', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered 'No (N)'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-04T20:33:05', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '2311d447-c3f4-463d-8d25-1b5aac56cf00' User entered '04 Aug 2020 20:33'	System	05 Aug 2020 02:33:06
	System	05 Aug 2020 02:33:06

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Aug 2020 20:19'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 2'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:51', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:54', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:31:57', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:32:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:32:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'None (0)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17



US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:32:09', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered 'No (N)'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-05T14:32:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '06bd02bb-a7fb-4d72-8266-8ce6438472f7' User entered '05 Aug 2020 14:32'	System	05 Aug 2020 20:32:17
	System	05 Aug 2020 20:32:17

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 3'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:20', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered 'None (0)'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:10:27', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1'	System	07 Aug 2020 00:11:36
User entered 'Some interference with activity (2)'	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1'	System	07 Aug 2020 00:11:36
User entered 'Some interference with activity (2)'	System	07 Aug 2020 00:11:36



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:11', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered 'None (0)'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered 'None (0)'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered 'None (0)'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:21', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered 'No (N)'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-06T18:11:33', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '064f348a-ef89-49d0-9689-e0a1e65ebab1' User entered '06 Aug 2020 18:11'	System	07 Aug 2020 00:11:36
	System	07 Aug 2020 00:11:36

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 4'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:32', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'None (0)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:45', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered 'No (N)'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-07T12:47:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '94403e39-35bb-4798-9f9d-d8d950e0ff15' User entered '07 Aug 2020 12:47'	System	07 Aug 2020 18:47:49
	System	07 Aug 2020 18:47:49



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 5'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 6'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:35', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:38', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:41', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:46', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'None (0)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:34:58', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered 'No (N)'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T09:35:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8b41d0df-fb67-4fa1-8f96-2e625520815d' User entered '10 Aug 2020 09:35'	System	10 Aug 2020 15:35:07
	System	10 Aug 2020 15:35:07

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 22:39:59



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 7'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:24', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:26', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:29', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:31', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:34', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:36', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'None (0)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

US3142100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:41', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered 'No (N)'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46



**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-08-10T12:55:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4e9a7539-9b3b-4720-819d-0124720b86db' User entered '10 Aug 2020 12:55'	System	10 Aug 2020 18:55:46
	System	10 Aug 2020 18:55:46

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 22:39:59

**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:44
User entered 'Yes (Y)'	Jami Wagner (b) (4)	20 Aug 2020 20:11:29

**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:46
User entered '12 Aug 2020'	Jami Wagner (b) (4)	20 Aug 2020 20:11:29

**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:48
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	20 Aug 2020 20:11:29

**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:50:50
User entered empty.	Jami Wagner (b) (4)	20 Aug 2020 20:11:29

**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	20 Aug 2020 20:11:34



**US3142100**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	20 Aug 2020 20:11:34

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:35
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	24 Aug 2020 15:15:26

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:37
User entered '19 Aug 2020'	Dalia Jeronimo (b) (4)	24 Aug 2020 15:15:26

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:40
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	24 Aug 2020 15:15:26

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:42
User entered empty.	Dalia Jeronimo (b) (4)	24 Aug 2020 15:15:26

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:51:56
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	24 Aug 2020 15:15:32

**US3142100**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	24 Aug 2020 15:15:32

**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:28
User entered 'Yes (Y)'	Jami Wagner (b) (4)	03 Sep 2020 01:37:24



**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:30
User entered '28 Aug 2020'	Jami Wagner (b) (4)	03 Sep 2020 01:37:24

**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:32
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	03 Sep 2020 01:37:24

**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:34
User entered empty.	Jami Wagner (b) (4)	03 Sep 2020 01:37:24

**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:52:44
User entered 'Yes (Y)'	Jami Wagner (b) (4)	03 Sep 2020 01:37:30

**US3142100**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	03 Sep 2020 01:37:30

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:53:32
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:12:16

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:53:34
User entered '3 Sep 2020'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:12:16

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:53:36
User entered 'Clinic (Clinic)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:12:16



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'VISIT2'	System	15 Sep 2020 19:12:16

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Pre-Dose (PREDOSE)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '3 Sep 2020'	(b) (4) Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:11:13
User entered '11:15' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:11:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '3 Sep 2020 11:15'	System	19 Oct 2020 16:11:13
User entered empty.	System	15 Sep 2020 19:14:21

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:11:13
User entered '98.8' F reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:11:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Oct 2020 16:11:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Oct 2020 16:11:27
User entered 'Other (Other)' reason for change: Data Meghan York Entry Error	(b) (4)	19 Oct 2020 16:11:27
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 16:11:13
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'temporal' reason for change: Data Entry Error	(b) (4)	
	Meghan York (b) (4)	19 Oct 2020 16:11:27
User entered empty.	(b) (4)	
	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:11:13
User entered '98' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:11:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'bpm'	System	19 Oct 2020 16:11:13
User entered empty.	System	15 Sep 2020 19:14:21

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System	System	19 Oct 2020 16:11:13
data change (Site from System).		
User entered '13' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:11:13
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'breaths/min'	System	19 Oct 2020 16:11:13
User entered empty.	System	15 Sep 2020 19:14:21

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Oct 2020 16:11:13
User entered '118' reason for change: Data Entry Error	Meghan York (b) (4)	19 Oct 2020 16:11:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	19 Oct 2020 16:11:13
User entered empty.	System	15 Sep 2020 19:14:21

US3142100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Oct 2020 16:11:13
Query 'Data is required. Please provide.' answered by System	System	19 Oct 2020 16:11:13
data change (Site from System).		
User entered '85' reason for change: Data Entry	Meghan York (b) (4)	19 Oct 2020 16:11:13
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 19:14:21
User entered empty.	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21
	(b) (4)	



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	19 Oct 2020 16:11:13
User entered empty.	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Post-Dose (POSTDOSE)'	Dalia Jeronimo (b) (4) (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:20
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:22
User entered '3 Sep 2020'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:24
User entered '12:42'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '3 Sep 2020 12:42'	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:26
User entered '98.1' F	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:28
User entered 'Other (Other)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:30
User entered 'Temporal'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:32
User entered '80'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'bpm'	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:37
User entered '13'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'breaths/min'	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:40
User entered '139'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:56:45
User entered '87'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:21



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	15 Sep 2020 19:14:21

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:26
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:32

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:28
User entered '3 Sep 2020'	Dalia Jeronimo (b) (4)	15 Sep 2020 19:14:32

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:47
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:50
User entered empty.	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59

US3142100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:52
User entered empty.	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:56
User entered '03 Sep 2020'	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:08:59
User entered '12:12'	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '03 Sep 2020 12:12'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:09:04
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4)	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
DataPoint Verified.		27 Oct 2020 17:09:07
User entered 'ONCE'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:09:25
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Oct 2020 16:11:49

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:09:27
User entered '3 Sep 2020'	Meghan York (b) (4)	19 Oct 2020 16:11:49

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:10:08
User entered '11:36'	Meghan York (b) (4)	19 Oct 2020 16:11:49



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '3 Sep 2020 11:36'	System	19 Oct 2020 16:11:49

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '3 Sep 2020'	Meghan York (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:10:41
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:10:43
User entered '11:30'	Meghan York (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '3 Sep 2020 11:30'	System	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:11:01
User entered 'Yes (Y)'	Meghan York (b) (4)	19 Oct 2020 16:12:13



**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:11:03
User entered '11:30'	Meghan York (b) (4)	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '3 Sep 2020 11:30'	System	19 Oct 2020 16:12:13

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	14 Sep 2020 16:16:54

**US3142100**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '1'	System	14 Sep 2020 16:16:54

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 12:32'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:02'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:57'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 2'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:05', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f8337211-a007-44fb-b529-3bf877a62a2d' User entered 'Yes (Y)'	System	05 Sep 2020 14:10:31
	System	05 Sep 2020 14:10:31



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f8337211-a007-44fb-b529-3bf877a62a2d' User entered '97.4'	System	05 Sep 2020 14:10:31
	System	05 Sep 2020 14:10:31

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:23', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f8337211-a007-44fb-b529-3bf877a62a2d' User entered 'No (N)'	System	05 Sep 2020 14:10:31
	System	05 Sep 2020 14:10:31

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f8337211-a007-44fb-b529-3bf877a62a2d' User entered '05 Sep 2020 08:10'	System	05 Sep 2020 14:10:31
	System	05 Sep 2020 14:10:31

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 3'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3916ab57-3088-4d1e-bfe7-6fb826595ce3' User entered 'Yes (Y)'	System	06 Sep 2020 00:31:27
	System	06 Sep 2020 00:31:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:31:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3916ab57-3088-4d1e-bfe7-6fb826595ce3' User entered '98.5'	System	06 Sep 2020 00:31:27
	System	06 Sep 2020 00:31:27



US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:31:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3916ab57-3088-4d1e-bfe7-6fb826595ce3' User entered 'No (N)'	System	06 Sep 2020 00:31:27
	System	06 Sep 2020 00:31:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:31:23', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3916ab57-3088-4d1e-bfe7-6fb826595ce3' User entered '05 Sep 2020 18:31'	System	06 Sep 2020 00:31:27
	System	06 Sep 2020 00:31:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 4'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a562ad25-13d1-4f60-9d13-117a84a10305' User entered 'Yes (Y)'	System	07 Sep 2020 01:42:27
	System	07 Sep 2020 01:42:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a562ad25-13d1-4f60-9d13-117a84a10305' User entered '97.5'	System	07 Sep 2020 01:42:27
	System	07 Sep 2020 01:42:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:21', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a562ad25-13d1-4f60-9d13-117a84a10305'	System	07 Sep 2020 01:42:27
User entered 'No (N)'	System	07 Sep 2020 01:42:27



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:25', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a562ad25-13d1-4f60-9d13-117a84a10305' User entered '06 Sep 2020 19:42'	System	07 Sep 2020 01:42:27
	System	07 Sep 2020 01:42:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 5'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:02:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 6'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ab73126e-8fa4-46ac-b271-37d714bfa33f' User entered 'Yes (Y)'	System	08 Sep 2020 21:21:39
	System	08 Sep 2020 21:21:39

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:02:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:25', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ab73126e-8fa4-46ac-b271-37d714bfa33f' User entered '98.4'	System	08 Sep 2020 21:21:39
	System	08 Sep 2020 21:21:39

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:29', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ab73126e-8fa4-46ac-b271-37d714bfa33f' User entered 'No (N)'	System	08 Sep 2020 21:21:39
	System	08 Sep 2020 21:21:39



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'ab73126e-8fa4-46ac-b271-37d714bfa33f' User entered '08 Sep 2020 15:21'	System	08 Sep 2020 21:21:39
	System	08 Sep 2020 21:21:39

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 7'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:47:39', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '763bb054-b128-493e-80ed-cec43f860591' User entered 'Yes (Y)'	System	10 Sep 2020 13:48:12
	System	10 Sep 2020 13:48:12

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '763bb054-b128-493e-80ed-cec43f860591' User entered '98.3'	System	10 Sep 2020 13:48:12
	System	10 Sep 2020 13:48:12

US3142100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:05', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '763bb054-b128-493e-80ed-cec43f860591' User entered 'No (N)'	System	10 Sep 2020 13:48:12
	System	10 Sep 2020 13:48:12

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:09', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '763bb054-b128-493e-80ed-cec43f860591' User entered '10 Sep 2020 07:48'	System	10 Sep 2020 13:48:12
	System	10 Sep 2020 13:48:12



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 12:32'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:02'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:57'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 2'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9b212867-6636-4ebe-a303-8f1b3ce56038'	System	05 Sep 2020 14:10:57
User entered 'None (1)'	System	05 Sep 2020 14:10:57



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9b212867-6636-4ebe-a303-8f1b3ce56038' User entered 'No (N)'	System	05 Sep 2020 14:10:57
	System	05 Sep 2020 14:10:57

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:47', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9b212867-6636-4ebe-a303-8f1b3ce56038' User entered 'No (N)'	System	05 Sep 2020 14:10:57
	System	05 Sep 2020 14:10:57

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:51', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9b212867-6636-4ebe-a303-8f1b3ce56038'	System	05 Sep 2020 14:10:57
User entered 'None (1)'	System	05 Sep 2020 14:10:57

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:10:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9b212867-6636-4ebe-a303-8f1b3ce56038' User entered '05 Sep 2020 08:10'	System	05 Sep 2020 14:10:57
	System	05 Sep 2020 14:10:57

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 3'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:29:42', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '80937621-cf5b-479c-9466-786ed690dd54'	System	06 Sep 2020 00:29:59
User entered 'None (1)'	System	06 Sep 2020 00:29:59



US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:29:45', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '80937621-cf5b-479c-9466-786ed690dd54' User entered 'No (N)'	System	06 Sep 2020 00:29:59
	System	06 Sep 2020 00:29:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:29:49', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '80937621-cf5b-479c-9466-786ed690dd54' User entered 'No (N)'	System	06 Sep 2020 00:29:59
	System	06 Sep 2020 00:29:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:29:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '80937621-cf5b-479c-9466-786ed690dd54' User entered 'None (1)'	System	06 Sep 2020 00:29:59
	System	06 Sep 2020 00:29:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:29:56', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '80937621-cf5b-479c-9466-786ed690dd54' User entered '05 Sep 2020 18:29'	System	06 Sep 2020 00:29:59
	System	06 Sep 2020 00:29:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 4'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4ada735b-4b22-472a-ad81-78cc70e39646' User entered 'None (1)'	System	07 Sep 2020 01:43:23
	System	07 Sep 2020 01:43:23



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4ada735b-4b22-472a-ad81-78cc70e39646' User entered 'No (N)'	System	07 Sep 2020 01:43:23
	System	07 Sep 2020 01:43:23

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:42:59', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4ada735b-4b22-472a-ad81-78cc70e39646' User entered 'No (N)'	System	07 Sep 2020 01:43:23
	System	07 Sep 2020 01:43:23

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4ada735b-4b22-472a-ad81-78cc70e39646' User entered 'None (1)'	System	07 Sep 2020 01:43:23
	System	07 Sep 2020 01:43:23

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:21', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4ada735b-4b22-472a-ad81-78cc70e39646' User entered '06 Sep 2020 19:43'	System	07 Sep 2020 01:43:23
	System	07 Sep 2020 01:43:23

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 5'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 6'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:46', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd0967f36-f73a-4bc2-b330-ac0c2de088f9'	System	08 Sep 2020 21:22:06
User entered 'None (1)'	System	08 Sep 2020 21:22:06

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:49', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd0967f36-f73a-4bc2-b330-ac0c2de088f9' User entered 'No (N)'	System	08 Sep 2020 21:22:06
	System	08 Sep 2020 21:22:06

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:21:53', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd0967f36-f73a-4bc2-b330-ac0c2de088f9' User entered 'No (N)'	System	08 Sep 2020 21:22:06
	System	08 Sep 2020 21:22:06

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:01', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd0967f36-f73a-4bc2-b330-ac0c2de088f9'	System	08 Sep 2020 21:22:06
User entered 'None (1)'	System	08 Sep 2020 21:22:06

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd0967f36-f73a-4bc2-b330-ac0c2de088f9' User entered '08 Sep 2020 15:22'	System	08 Sep 2020 21:22:06
	System	08 Sep 2020 21:22:06

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 7'	System	03 Sep 2020 18:36:59

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c687c48a-840b-46f7-b312-8573c885980e' User entered 'None (1)'	System	10 Sep 2020 13:48:36
	System	10 Sep 2020 13:48:36

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c687c48a-840b-46f7-b312-8573c885980e' User entered 'No (N)'	System	10 Sep 2020 13:48:36
	System	10 Sep 2020 13:48:36

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:22', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c687c48a-840b-46f7-b312-8573c885980e' User entered 'No (N)'	System	10 Sep 2020 13:48:36
	System	10 Sep 2020 13:48:36

US3142100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:29', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c687c48a-840b-46f7-b312-8573c885980e' User entered 'None (1)'	System	10 Sep 2020 13:48:36
	System	10 Sep 2020 13:48:36

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:32', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c687c48a-840b-46f7-b312-8573c885980e' User entered '10 Sep 2020 07:48'	System	10 Sep 2020 13:48:36
	System	10 Sep 2020 13:48:36

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 12:32'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:02'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '03 Sep 2020 15:57'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 2'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:07', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:10', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:13', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered 'None (0)'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:20', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53'	System	05 Sep 2020 14:11:25
User entered 'No (N)'	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T08:11:22', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '28cc4fa5-cdb5-4021-8e9d-f63054e5ca53' User entered '05 Sep 2020 08:11'	System	05 Sep 2020 14:11:25
	System	05 Sep 2020 14:11:25

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 3'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:07', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:10', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:24', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered 'None (0)'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59'	System	06 Sep 2020 00:30:44
User entered 'No (N)'	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-05T18:30:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '41863117-f13e-4140-b6b2-c41b50ae4a59' User entered '05 Sep 2020 18:30'	System	06 Sep 2020 00:30:44
	System	06 Sep 2020 00:30:44

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 4'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:25', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:42', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'None (0)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:57', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered 'No (N)'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-06T19:43:59', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1348e9b8-dae5-4999-af2c-bca2d79a57e1' User entered '06 Sep 2020 19:43'	System	07 Sep 2020 01:44:00
	System	07 Sep 2020 01:44:00

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 5'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 6'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:08', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:11', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:14', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32



**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:22', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered 'None (0)'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:25', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35'	System	08 Sep 2020 21:22:32
User entered 'No (N)'	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-08T15:22:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1e00a8f6-dc10-4644-946b-8402ac429e35' User entered '08 Sep 2020 15:22'	System	08 Sep 2020 21:22:32
	System	08 Sep 2020 21:22:32

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	03 Sep 2020 18:36:59
User entered 'Day 7'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:39', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:43', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07



US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:46', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:50', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:53', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:48:56', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'None (0)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

US3142100

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:02:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:49:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered 'No (N)'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-09-10T07:49:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd877db87-0b5c-4d13-84e4-98b6ea2ebbd8' User entered '10 Sep 2020 07:49'	System	10 Sep 2020 13:49:07
	System	10 Sep 2020 13:49:07

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:36:59

**US3142100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:02:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:36:59



**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:03
User entered 'Yes (Y)'	Jami Wagner (b) (4)	14 Sep 2020 17:43:21

**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:04
User entered '10 Sep 2020'	Jami Wagner (b) (4)	14 Sep 2020 17:43:21

**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:07
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	14 Sep 2020 17:43:21

**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:08
User entered empty.	Jami Wagner (b) (4)	14 Sep 2020 17:43:21

**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:19
User entered 'Yes (Y)'	Jami Wagner (b) (4)	14 Sep 2020 17:43:28

**US3142100**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	14 Sep 2020 17:43:28

**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	18 Sep 2020 15:39:12

**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '17 Sep 2020'	Dalia Jeronimo (b) (4)	18 Sep 2020 15:39:12



**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dalia Jeronimo (b) (4)	18 Sep 2020 15:39:12

**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4)	
	Dalia Jeronimo (b) (4)	18 Sep 2020 15:39:12
	(b) (4)	

**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	18 Sep 2020 15:39:18

**US3142100**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered '1'	System	18 Sep 2020 15:39:18

**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:47
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:23:25

**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:49
User entered '24 Sep 2020'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:23:25

**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:51
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:23:25

**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:17:53
User entered empty.	Dalia Jeronimo (b) (4)	25 Sep 2020 14:23:25



**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:18:03
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	25 Sep 2020 14:23:34

**US3142100**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	25 Sep 2020 14:23:34

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:20:49
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 14:54:07

US3142100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:32:26
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		22 Oct 2020 19:00:52
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Information provided is correct.' (Site from System).	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:54:21
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Oct 2020 14:54:07
User entered '20 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:54:07

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:32:20
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	22 Oct 2020 14:54:07

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'VISIT3'	System	22 Oct 2020 14:54:07

US3142100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Per CDM: Vital signs is performed on 20 Oct 2020 for Convalescence Visit Day 28 as well as Visit 3 Day 57 , kindly review if they are duplicates else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 05:57:44
Query 'Per CDM: Vital signs is performed on 20 Oct 2020 for Convalescence Visit Day 28 as well as Visit 3 Day 57 , kindly review if they are duplicates else clarify' answered with 'data is now correct ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 19:00:13
User opened query 'Per CDM: Vital signs is performed on 20 Oct 2020 for Convalescence Visit Day 28 as well as Visit 3 Day 57 , kindly review if they are duplicates else clarify' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:06:31
DataPoint Verified.		27 Oct 2020 18:42:57
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:42:58
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46



**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:01
User entered '13:59'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '20 Oct 2020 13:59'	System	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:05
User entered '97.6' F	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:07
User entered 'Other (Other)'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:14
User entered 'Temporal'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:17
User entered '77'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'bpm'	System	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:19
User entered '10'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46



**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'breaths/min'	System	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:21
User entered '124'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:23
User entered '83'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered 'mmHg'	System	22 Oct 2020 14:55:46

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:40
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:54



**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:43:42
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 14:55:54

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 14:56:15

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 14:56:15

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:12'	Shelby Pickle (b) (4)	22 Oct 2020 14:56:15

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '20 Oct 2020 14:12'	System	22 Oct 2020 14:56:15

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:19:32
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 14:56:21

**US3142100**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:13
User entered '1'	System	22 Oct 2020 14:56:21

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 64'	System	04 Aug 2020 22:39:59



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-05T15:22:32', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e4d36ca8-4efe-46f8-b672-b6134eca5772'	System	05 Oct 2020 21:23:43
User entered 'Yes (Y)'	System	05 Oct 2020 21:23:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-05T15:23:08', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e4d36ca8-4efe-46f8-b672-b6134eca5772'	System	05 Oct 2020 21:23:43
User entered 'No (N)'	System	05 Oct 2020 21:23:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-05T15:23:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e4d36ca8-4efe-46f8-b672-b6134eca5772'	System	05 Oct 2020 21:23:43
User entered 'No (N)'	System	05 Oct 2020 21:23:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-05T15:23:21', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e4d36ca8-4efe-46f8-b672-b6134eca5772'	System	05 Oct 2020 21:23:43
User entered 'No (N)'	System	05 Oct 2020 21:23:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-05T15:23:41', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'e4d36ca8-4efe-46f8-b672-b6134eca5772' User entered '05 Oct 2020 15:23:41'	System	05 Oct 2020 21:23:43
	System	05 Oct 2020 21:23:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 71'	System	04 Aug 2020 22:39:59



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-11T15:12:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'eb98df48-99ba-4627-b132-08eb6b03d73c' User entered 'Yes (Y)'	System	11 Oct 2020 21:13:33
	System	11 Oct 2020 21:13:33

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-11T15:13:10', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'eb98df48-99ba-4627-b132-08eb6b03d73c' User entered 'No (N)'	System	11 Oct 2020 21:13:33
	System	11 Oct 2020 21:13:33

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-11T15:13:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'eb98df48-99ba-4627-b132-08eb6b03d73c' User entered 'No (N)'	System	11 Oct 2020 21:13:33
	System	11 Oct 2020 21:13:33

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-11T15:13:26', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'eb98df48-99ba-4627-b132-08eb6b03d73c' User entered 'No (N)'	System	11 Oct 2020 21:13:33
	System	11 Oct 2020 21:13:33

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-11T15:13:30', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'eb98df48-99ba-4627-b132-08eb6b03d73c' User entered '11 Oct 2020 15:13:30'	System	11 Oct 2020 21:13:33
	System	11 Oct 2020 21:13:33

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 78'	System	04 Aug 2020 22:39:59



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-21T18:07:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1426493a-f6b8-4fad-96a2-faa2d1c13bb9'	System	22 Oct 2020 00:07:19
User entered 'No (N)'	System	22 Oct 2020 00:07:19

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-21T18:07:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1426493a-f6b8-4fad-96a2-faa2d1c13bb9'	System	22 Oct 2020 00:07:19
User entered 'No (N)'	System	22 Oct 2020 00:07:19

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-10-21T18:07:16', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '1426493a-f6b8-4fad-96a2-faa2d1c13bb9' User entered '21 Oct 2020 18:07:16'	System	22 Oct 2020 00:07:19
	System	22 Oct 2020 00:07:19

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 92'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-04T17:00:31', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f4423b04-90a8-4d57-b695-bba9105f078c' User entered 'No (N)'	System	05 Nov 2020 00:00:45
	System	05 Nov 2020 00:00:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-04T17:00:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f4423b04-90a8-4d57-b695-bba9105f078c' User entered 'No (N)'	System	05 Nov 2020 00:00:45
	System	05 Nov 2020 00:00:45



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-04T17:00:43', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'f4423b04-90a8-4d57-b695-bba9105f078c' User entered '04 Nov 2020 17:00:43'	System	05 Nov 2020 00:00:45
	System	05 Nov 2020 00:00:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 99'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-08T15:04:11', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4c964e39-e656-4497-98bf-3639994701ba' User entered 'No (N)'	System	08 Nov 2020 22:04:21
	System	08 Nov 2020 22:04:21

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-08T15:04:16', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4c964e39-e656-4497-98bf-3639994701ba' User entered 'No (N)'	System	08 Nov 2020 22:04:21
	System	08 Nov 2020 22:04:21

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-08T15:04:20', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '4c964e39-e656-4497-98bf-3639994701ba' User entered '08 Nov 2020 15:04:20'	System	08 Nov 2020 22:04:21
	System	08 Nov 2020 22:04:21

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 22:39:59



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered 'Day 106'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-15T20:19:54', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '966850c9-0c39-45e6-80cb-5af29412f9d0'	System	16 Nov 2020 03:20:36
User entered 'No (N)'	System	16 Nov 2020 03:20:36

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-15T20:20:04', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '966850c9-0c39-45e6-80cb-5af29412f9d0'	System	16 Nov 2020 03:20:36
User entered 'No (N)'	System	16 Nov 2020 03:20:36

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-15T20:20:32', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '966850c9-0c39-45e6-80cb-5af29412f9d0' User entered '15 Nov 2020 20:20:32'	System	16 Nov 2020 03:20:36
	System	16 Nov 2020 03:20:36

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:35:27
Data entry locked.	System	04 Aug 2020 22:39:59
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 22:39:59

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-23T07:38:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8222e50b-0c73-4c8c-bd88-3c9126d5d255' User entered 'No (N)'	System	23 Nov 2020 14:39:02

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-23T07:38:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8222e50b-0c73-4c8c-bd88-3c9126d5d255'	System	23 Nov 2020 14:39:02
User entered 'No (N)'	System	23 Nov 2020 14:39:02

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-23T07:39:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '8222e50b-0c73-4c8c-bd88-3c9126d5d255'	System	23 Nov 2020 14:39:02
User entered '23 Nov 2020 07:39:00'	System	23 Nov 2020 14:39:02

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-28T22:13:15', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9ae15035-fc4b-40b0-bced-797e5d9ec23e' User entered 'No (N)'	System	29 Nov 2020 05:13:32
	System	29 Nov 2020 05:13:32

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-28T22:13:24', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9ae15035-fc4b-40b0-bced-797e5d9ec23e' User entered 'No (N)'	System	29 Nov 2020 05:13:32
	System	29 Nov 2020 05:13:32



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-11-28T22:13:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9ae15035-fc4b-40b0-bced-797e5d9ec23e' User entered '28 Nov 2020 22:13:28'	System	29 Nov 2020 05:13:32
	System	29 Nov 2020 05:13:32

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-05T13:48:37', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c4b250e3-354a-4aa6-a687-c5b43ad7ee2e' User entered 'No (N)'	System	05 Dec 2020 20:48:53
	System	05 Dec 2020 20:48:53

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-05T13:48:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c4b250e3-354a-4aa6-a687-c5b43ad7ee2e' User entered 'No (N)'	System	05 Dec 2020 20:48:53
	System	05 Dec 2020 20:48:53

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-05T13:48:47', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c4b250e3-354a-4aa6-a687-c5b43ad7ee2e' User entered '05 Dec 2020 13:48:47'	System	05 Dec 2020 20:48:53
	System	05 Dec 2020 20:48:53

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-14T11:29:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e0d232c-3eae-4913-bc50-140355c54b00'	System	14 Dec 2020 18:29:54
User entered 'No (N)'	System	14 Dec 2020 18:29:54

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-14T11:29:35', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e0d232c-3eae-4913-bc50-140355c54b00'	System	14 Dec 2020 18:29:54
User entered 'No (N)'	System	14 Dec 2020 18:29:54

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-14T11:29:52', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '7e0d232c-3eae-4913-bc50-140355c54b00' User entered '14 Dec 2020 11:29:52'	System	14 Dec 2020 18:29:54
	System	14 Dec 2020 18:29:54

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-18T13:22:26', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a61bf6e8-710c-46f3-b03f-0e43f010e70e' User entered 'Yes (Y)'	System	18 Dec 2020 20:23:22
	System	18 Dec 2020 20:23:22

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-18T13:22:31', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a61bf6e8-710c-46f3-b03f-0e43f010e70e' User entered 'No (N)'	System	18 Dec 2020 20:23:22
	System	18 Dec 2020 20:23:22

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-18T13:23:12', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a61bf6e8-710c-46f3-b03f-0e43f010e70e' User entered 'No (N)'	System	18 Dec 2020 20:23:22
	System	18 Dec 2020 20:23:22

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-18T13:23:16', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a61bf6e8-710c-46f3-b03f-0e43f010e70e' User entered 'No (N)'	System	18 Dec 2020 20:23:22
	System	18 Dec 2020 20:23:22

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-18T13:23:19', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'a61bf6e8-710c-46f3-b03f-0e43f010e70e' User entered '18 Dec 2020 13:23:19'	System	18 Dec 2020 20:23:22
	System	18 Dec 2020 20:23:22

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-27T18:05:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c1e4cb05-695c-4330-8904-41874900c508'	System	28 Dec 2020 01:06:45
User entered 'Yes (Y)'	System	28 Dec 2020 01:06:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-27T18:05:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c1e4cb05-695c-4330-8904-41874900c508' User entered 'No (N)'	System	28 Dec 2020 01:06:45
	System	28 Dec 2020 01:06:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-27T18:06:09', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c1e4cb05-695c-4330-8904-41874900c508' User entered 'No (N)'	System	28 Dec 2020 01:06:45
	System	28 Dec 2020 01:06:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-27T18:06:13', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c1e4cb05-695c-4330-8904-41874900c508' User entered 'No (N)'	System	28 Dec 2020 01:06:45
	System	28 Dec 2020 01:06:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2020-12-27T18:06:41', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'c1e4cb05-695c-4330-8904-41874900c508' User entered '27 Dec 2020 18:06:41'	System	28 Dec 2020 01:06:45
	System	28 Dec 2020 01:06:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-04T11:59:29', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3d1ad06a-d39f-4cc4-be42-988442f8c8ac'	System	04 Jan 2021 18:59:52
User entered 'No (N)'	System	04 Jan 2021 18:59:52

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-04T11:59:36', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3d1ad06a-d39f-4cc4-be42-988442f8c8ac'	System	04 Jan 2021 18:59:52
User entered 'No (N)'	System	04 Jan 2021 18:59:52

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-04T11:59:50', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3d1ad06a-d39f-4cc4-be42-988442f8c8ac' User entered '04 Jan 2021 11:59:50'	System	04 Jan 2021 18:59:52
	System	04 Jan 2021 18:59:52

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-07T16:01:48', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '295b65a2-a6ae-48a4-92b3-9fe821c30031' User entered 'No (N)'	System	07 Jan 2021 23:02:10
	System	07 Jan 2021 23:02:10

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-07T16:01:53', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '295b65a2-a6ae-48a4-92b3-9fe821c30031' User entered 'No (N)'	System	07 Jan 2021 23:02:10



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-07T16:01:56', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '295b65a2-a6ae-48a4-92b3-9fe821c30031' User entered '07 Jan 2021 16:01:56'	System	07 Jan 2021 23:02:10
	System	07 Jan 2021 23:02:10

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-15T17:06:01', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '87b03884-360a-4645-b249-89b7259adb62'	System	16 Jan 2021 00:06:14
User entered 'No (N)'	System	16 Jan 2021 00:06:14

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-15T17:06:07', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '87b03884-360a-4645-b249-89b7259adb62'	System	16 Jan 2021 00:06:14
User entered 'No (N)'	System	16 Jan 2021 00:06:14

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-15T17:06:11', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '87b03884-360a-4645-b249-89b7259adb62'	System	16 Jan 2021 00:06:14
User entered '15 Jan 2021 17:06:11'	System	16 Jan 2021 00:06:14

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-21T09:24:28', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '57e1eb1d-b045-40ee-9597-752f4ea0b6eb' User entered 'No (N)'	System	21 Jan 2021 16:24:45
	System	21 Jan 2021 16:24:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-21T09:24:35', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '57e1eb1d-b045-40ee-9597-752f4ea0b6eb' User entered 'No (N)'	System	21 Jan 2021 16:24:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-21T09:24:42', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '57e1eb1d-b045-40ee-9597-752f4ea0b6eb' User entered '21 Jan 2021 09:24:42'	System	21 Jan 2021 16:24:45
	System	21 Jan 2021 16:24:45

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-29T15:55:57', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd1af0f9d-0009-4d93-be72-20c6d7924228'	System	29 Jan 2021 22:56:07
User entered 'No (N)'	System	29 Jan 2021 22:56:07

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-29T15:56:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd1af0f9d-0009-4d93-be72-20c6d7924228'	System	29 Jan 2021 22:56:07
User entered 'No (N)'	System	29 Jan 2021 22:56:07

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-01-29T15:56:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'd1af0f9d-0009-4d93-be72-20c6d7924228' User entered '29 Jan 2021 15:56:06'	System	29 Jan 2021 22:56:07
	System	29 Jan 2021 22:56:07

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-07T17:59:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '26f1de81-d152-4a49-8dd3-f08ff060336d' User entered 'No (N)'	System	08 Feb 2021 00:59:56
	System	08 Feb 2021 00:59:56

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-07T17:59:47', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '26f1de81-d152-4a49-8dd3-f08ff060336d' User entered 'No (N)'	System	08 Feb 2021 00:59:56
	System	08 Feb 2021 00:59:56



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-07T17:59:53', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '26f1de81-d152-4a49-8dd3-f08ff060336d' User entered '07 Feb 2021 17:59:53'	System	08 Feb 2021 00:59:56
	System	08 Feb 2021 00:59:56

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-11T14:03:44', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9716c35b-9310-4fcd-bfe0-fa6c4fa6e2dc' User entered 'No (N)'	System	11 Feb 2021 21:04:12
	System	11 Feb 2021 21:04:12

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-11T14:04:02', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9716c35b-9310-4fcd-bfe0-fa6c4fa6e2dc' User entered 'No (N)'	System	11 Feb 2021 21:04:12

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-11T14:04:06', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9716c35b-9310-4fcd-bfe0-fa6c4fa6e2dc' User entered '11 Feb 2021 14:04:06'	System	11 Feb 2021 21:04:12
	System	11 Feb 2021 21:04:12

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-18T10:25:55', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3129970a-fb67-48e6-bb1a-3cccaffa2a91' User entered 'Yes (Y)'	System	18 Feb 2021 17:26:43
	System	18 Feb 2021 17:26:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-18T10:26:07', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3129970a-fb67-48e6-bb1a-3cccaffa2a91' User entered 'No (N)'	System	18 Feb 2021 17:26:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-18T10:26:17', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3129970a-fb67-48e6-bb1a-3cccaffa2a91' User entered 'No (N)'	System	18 Feb 2021 17:26:43
	System	18 Feb 2021 17:26:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-18T10:26:23', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3129970a-fb67-48e6-bb1a-3cccaffa2a91' User entered 'No (N)'	System	18 Feb 2021 17:26:43
	System	18 Feb 2021 17:26:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-18T10:26:40', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '3129970a-fb67-48e6-bb1a-3cccaffa2a91' User entered '18 Feb 2021 10:26:40'	System	18 Feb 2021 17:26:43
	System	18 Feb 2021 17:26:43

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-27T13:38:25-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9224f49a-14db-4579-b376-6e27dcdf1862'	System	27 Feb 2021 20:38:37
User entered 'No (N)'	System	27 Feb 2021 20:38:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-27T13:38:29-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9224f49a-14db-4579-b376-6e27dcdf1862'	System	27 Feb 2021 20:38:37
User entered 'No (N)'	System	27 Feb 2021 20:38:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-27T13:38:32-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9224f49a-14db-4579-b376-6e27dcdf1862' User entered '27 Feb 2021 20:38:32'	System	27 Feb 2021 20:38:37
	System	27 Feb 2021 20:38:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-06T12:51:35-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9e99bf70-b7ec-49e1-86f5-51115ccd4183'	System	06 Mar 2021 19:51:49
User entered 'No (N)'	System	06 Mar 2021 19:51:49

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-06T12:51:44-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9e99bf70-b7ec-49e1-86f5-51115ccd4183'	System	06 Mar 2021 19:51:49
User entered 'No (N)'	System	06 Mar 2021 19:51:49

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-06T12:51:47-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '9e99bf70-b7ec-49e1-86f5-51115ccd4183' User entered '06 Mar 2021 12:51:47'	System	06 Mar 2021 19:51:49
	System	06 Mar 2021 19:51:49

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-12T17:03:09-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '6a4f916a-5662-4b1c-a425-59070b91e652'	System	13 Mar 2021 00:07:23
User entered 'Yes (Y)'	System	13 Mar 2021 00:07:23

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-12T17:03:13-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '6a4f916a-5662-4b1c-a425-59070b91e652'	System	13 Mar 2021 00:07:23
User entered 'No (N)'	System	13 Mar 2021 00:07:23



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-12T17:04:14-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '6a4f916a-5662-4b1c-a425-59070b91e652'	System	13 Mar 2021 00:07:23
User entered 'No (N)'	System	13 Mar 2021 00:07:23

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-12T17:03:45-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '6a4f916a-5662-4b1c-a425-59070b91e652'	System	13 Mar 2021 00:07:23
User entered 'No (N)'	System	13 Mar 2021 00:07:23

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-12T17:04:17-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '6a4f916a-5662-4b1c-a425-59070b91e652'	System	13 Mar 2021 00:07:23
User entered '12 Mar 2021 17:04:17'	System	13 Mar 2021 00:07:23

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-18T21:22:25-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'b18e54a3-4378-4982-bec9-b0c32d0e600a'	System	19 Mar 2021 03:22:42
User entered 'No (N)'	System	19 Mar 2021 03:22:42

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-18T21:22:33-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'b18e54a3-4378-4982-bec9-b0c32d0e600a'	System	19 Mar 2021 03:22:42
User entered 'No (N)'	System	19 Mar 2021 03:22:42



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-18T21:22:40-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'b18e54a3-4378-4982-bec9-b0c32d0e600a' User entered '18 Mar 2021 21:22:40'	System	19 Mar 2021 03:22:42
	System	19 Mar 2021 03:22:42

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-25T09:50:23-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '22861409-2c0a-42f8-946d-32c96b0b5c40'	System	25 Mar 2021 15:50:37
User entered 'No (N)'	System	25 Mar 2021 15:50:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-25T09:50:26-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '22861409-2c0a-42f8-946d-32c96b0b5c40'	System	25 Mar 2021 15:50:37
User entered 'No (N)'	System	25 Mar 2021 15:50:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-03-25T09:50:33-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '22861409-2c0a-42f8-946d-32c96b0b5c40' User entered '25 Mar 2021 09:50:33'	System	25 Mar 2021 15:50:37
	System	25 Mar 2021 15:50:37

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-01T09:15:54-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'da9e09a4-0bd2-4e9c-ad89-bb4b11d3a786'	System	01 Apr 2021 15:16:08
User entered 'No (N)'	System	01 Apr 2021 15:16:08

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-01T09:15:58-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'da9e09a4-0bd2-4e9c-ad89-bb4b11d3a786'	System	01 Apr 2021 15:16:08
User entered 'No (N)'	System	01 Apr 2021 15:16:08

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-01T09:16:02-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'da9e09a4-0bd2-4e9c-ad89-bb4b11d3a786'	System	01 Apr 2021 15:16:08
User entered '01 Apr 2021 09:16:02'	System	01 Apr 2021 15:16:08

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:57:38



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-08T15:30:30-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '354e4069-4082-4977-864f-dd5116bab357'	System	08 Apr 2021 21:31:20
User entered 'No (N)'	System	08 Apr 2021 21:31:20

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-08T15:30:52-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '354e4069-4082-4977-864f-dd5116bab357'	System	08 Apr 2021 21:31:20
User entered 'No (N)'	System	08 Apr 2021 21:31:20

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-08T15:31:15-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '354e4069-4082-4977-864f-dd5116bab357'	System	08 Apr 2021 21:31:20
User entered '08 Apr 2021 15:31:15'	System	08 Apr 2021 21:31:20

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:57:38

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-15T10:30:04-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'cbcd9e16-4f10-4162-a5f0-339cf18e4664'	System	15 Apr 2021 16:30:19
User entered 'No (N)'	System	15 Apr 2021 16:30:19

**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-15T10:30:10-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'cbcd9e16-4f10-4162-a5f0-339cf18e4664'	System	15 Apr 2021 16:30:19
User entered 'No (N)'	System	15 Apr 2021 16:30:19



**US3142100**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-15T10:30:13-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'cbcd9e16-4f10-4162-a5f0-339cf18e4664'	System	15 Apr 2021 16:30:19
User entered '15 Apr 2021 10:30:13'	System	15 Apr 2021 16:30:19

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-23T09:17:46-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'dd59efb7-d77a-46bf-9f28-ee6aeb483a75'	System	23 Apr 2021 15:18:01
User entered 'No (N)'	System	23 Apr 2021 15:18:01

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-23T09:17:52-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'dd59efb7-d77a-46bf-9f28-ee6aeb483a75'	System	23 Apr 2021 15:18:01
User entered 'No (N)'	System	23 Apr 2021 15:18:01

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-04-23T09:17:56-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'dd59efb7-d77a-46bf-9f28-ee6aeb483a75'	System	23 Apr 2021 15:18:01
User entered '23 Apr 2021 09:17:56'	System	23 Apr 2021 15:18:01

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-05-02T17:59:51-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'caaf263d-9c7f-4650-8c1f-dd3a7768308d'	System	03 May 2021 00:00:17
User entered 'No (N)'	System	03 May 2021 00:00:17

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

Have you been exposed to someone with 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 (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-05-02T18:00:01-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'caaf263d-9c7f-4650-8c1f-dd3a7768308d'	System	03 May 2021 00:00:17
User entered 'No (N)'	System	03 May 2021 00:00:17

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-05-02T18:00:11-06:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: 'caaf263d-9c7f-4650-8c1f-dd3a7768308d'	System	03 May 2021 00:00:17
User entered '02 May 2021 18:00:11'	System	03 May 2021 00:00:17

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:57:38



**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:57:38

**US3142100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:02:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:57:38
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:57:38



US3142100

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:02:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:23:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-27T13:38:41-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '35966de4-3f94-453b-b17b-74b0624a549e' User entered 'No (N)'	System	27 Feb 2021 20:38:55
	System	27 Feb 2021 20:38:55

**US3142100**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:23:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (716082C8-0CF8-489B-8518-CD7C8D0CD1E9)', Time: '2021-02-27T13:38:51-07:00', User OID: 'PatientReportedOutcome (US3142100)', ODM File OID: '35966de4-3f94-453b-b17b-74b0624a549e' User entered '27 Feb 2021 20:38:51'	System	27 Feb 2021 20:38:55
	System	27 Feb 2021 20:38:55

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	28 Oct 2020 15:08:39

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '27 Oct 2020'	Dalia Jeronimo (b) (4)	28 Oct 2020 15:08:39

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dalia Jeronimo (b) (4)	28 Oct 2020 15:08:39

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Dalia Jeronimo (b) (4)	28 Oct 2020 15:08:39

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	28 Oct 2020 15:09:44

**US3142100**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:20:07
User entered 'I'	System	28 Oct 2020 15:09:44



**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:55:52
User entered 'Yes (Y)'	Jami Wagner (b) (4)	07 Dec 2020 22:06:00

**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:55:52
User entered '1 Dec 2020'	Jami Wagner (b) (4)	07 Dec 2020 22:06:00

**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:55:52
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	07 Dec 2020 22:06:00

**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:55:52
User entered empty.	Jami Wagner (b) (4)	07 Dec 2020 22:06:00

**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	07 Dec 2020 22:06:26

**US3142100**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User entered 'I'	System	07 Dec 2020 22:06:26

**US3142100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:56:55
DataPoint Un-verified.		19 Jan 2021 16:56:51
DataPoint Verified.		19 Jan 2021 16:56:27
User entered 'Yes (Y)'	Jami Wagner (b) (4)	05 Jan 2021 22:45:34
	(b) (4)	

US3142100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:56:57
DataPoint Un-verified.		19 Jan 2021 16:56:53
DataPoint Verified.		19 Jan 2021 16:56:30
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		08 Jan 2021 03:43:21
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Information provided is correct' (Site from System).	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:56:59
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 22:45:34
User entered '5 Jan 2021'	Jami Wagner (b) (4) (b) (4)	05 Jan 2021 22:45:34



**US3142100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:56:30
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	05 Jan 2021 22:45:34

**US3142100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:56:30
User entered empty.	Jami Wagner (b) (4)	05 Jan 2021 22:45:34

**US3142100**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Jami Wagner (b) (4)	05 Jan 2021 22:45:39

**US3142100**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User entered '1'	System	05 Jan 2021 22:45:39

**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	23 Feb 2021 23:23:01

**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '01 Feb 2021'	Lisa Jackson (b) (4)	23 Feb 2021 23:23:01

**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	23 Feb 2021 23:23:01

**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Lisa Jackson (b) (4)	23 Feb 2021 23:23:01



**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:55:14

**US3142100**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:27:24
User entered '1'	System	11 Feb 2021 21:55:14

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:55:25

US3142100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 11 FEB2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:03:33
Query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 11 FEB2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you.' answered with 'data is now entered ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 19:06:43
User opened query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 11 FEB2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:04:09
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		22 Feb 2021 20:48:05
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'data entered as correct' (Site from System).		11 Feb 2021 21:55:52
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Feb 2021 21:55:25
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 21:55:25

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[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 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:55:25

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered 'VISIT4'	System	11 Feb 2021 21:55:25

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Shelby Pickle (b) (4)	29 Mar 2021 20:26:34



**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered empty.	System	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered empty.	System	29 Mar 2021 20:26:34

US3142100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34



**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered empty.	System	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered empty.	System	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) Shelby Pickle (b) (4)	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered empty.	System	29 Mar 2021 20:26:34

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12

US3142100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	11 Feb 2021 21:56:10
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 21:56:10
User entered 'No (N)'		11 Feb 2021 21:56:03
		11 Feb 2021 21:56:03



**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:56:03

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Jill York (b) (4)	23 Mar 2021 19:03:37

US3142100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Per GCL Lab Recon: Immunogenicity Sample for Visit 4 Day 209 dated 09Mar2021 is reported in PPD Central lab; however Sample dated 11Feb2021 is reported in EDC. Please reconcile and confirm correct date..' (Site from DM).	(b) (4)	12 Apr 2021 20:59:36
Query 'Per GCL Lab Recon: Immunogenicity Sample for Visit 4 Day 209 dated 09Mar2021 is reported in PPD Central lab; however Sample dated 11Feb2021 is reported in EDC. Please reconcile and confirm correct date..' answered with 'Day 29 = 09March2021 Day 209 = 11Feb2021' (Site from DM).	Jill York (b) (4)	09 Apr 2021 18:34:13
User opened query 'Per GCL Lab Recon: Immunogenicity Sample for Visit 4 Day 209 dated 09Mar2021 is reported in PPD Central lab; however Sample dated 11Feb2021 is reported in EDC. Please reconcile and confirm correct date..' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 01:54:02
User entered '11 Feb 2021'	Jill York (b) (4)	23 Mar 2021 19:03:37

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:24'	Jill York (b) (4)	23 Mar 2021 19:03:37

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered '11 Feb 2021 14:24'	System	23 Mar 2021 19:03:37

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:56:14

**US3142100**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:07:12
User entered 'I'	System	11 Feb 2021 21:56:14

**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 19:59:35
	(b) (4)	



**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '29 Mar 2021'	Jami Wagner (b) (4)	01 Apr 2021 19:59:35
	(b) (4)	

**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jami Wagner (b) (4) (b) (4)	01 Apr 2021 19:59:35

**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered empty.	Jami Wagner (b) (4)	01 Apr 2021 19:59:35
	(b) (4)	

**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Apr 2021 19:59:42
	(b) (4)	

**US3142100**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:59:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:44:22
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 16:00:50

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:02:03**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:44:23
User entered '12:30'	Shelby Pickle (b) (4)	29 Sep 2020 16:00:50

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:02:03**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:54
User entered '23 Sep 2020 12:30'	System	29 Sep 2020 16:00:50



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:44:25
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:00:50

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:02:03**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:54
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:44:28
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 16:00:50

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 1 (Day 1)'	(b) (4)	
	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:47:22
User closed query 'Please verify as source notes symptom Day 1 = 21Sep20 where subject had mild cough, SOB, muscle aches, body aches, headache, Congestion. Please add 21Sep2020 and 22Sep2020 as Day 1 and Day 2 (you can do on end of symptom log - doesn't need to be page 1). Then update symptom day # for remaining entries to match which symptom day it really was.' (Site from CRA).		10 Nov 2020 23:47:20
Query 'Please verify as source notes symptom Day 1 = 21Sep20 where subject had mild cough, SOB, muscle aches, body aches, headache, Congestion. Please add 21Sep2020 and 22Sep2020 as Day 1 and Day 2 (you can do on end of symptom log - doesn't need to be page 1). Then update symptom day # for remaining entries to match which symptom day it really was.' answered with 'Site can provide log lines for these, however, day 1 and 2 data is not available. The way protocol reads it seemed the Day 1 would commence at the visit, not prior. For symptom log included.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 23:16:00
User opened query 'Please verify as source notes symptom Day 1 = 21Sep20 where subject had mild cough, SOB, muscle aches, body aches, headache, Congestion. Please add 21Sep2020 and 22Sep2020 as Day 1 and Day 2 (you can do on end of symptom log - doesn't need to be page 1). Then update symptom day # for remaining entries to match which symptom day it really was.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:51:45
User closed query 'Per ETRTR: Please add Symptoms for missing days (also include Symptoms registered since Start day 21Sep20 of COVID-19), thanks.' (Site from CRA).		27 Oct 2020 22:14:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Date](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Please add Symptoms for missing days (also include Symptoms registered since Start day 21Sep20 of COVID-19), thanks.' answered with 'Site needs to consolidate onto single page.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	14 Oct 2020 16:29:06
User opened query 'Per ETRTR: Please add Symptoms for missing days (also include Symptoms registered since Start day 21Sep20 of COVID-19), thanks.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	02 Oct 2020 14:01:25
User entered '23 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:23
User entered '0'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:26
User entered '93'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	29 Sep 2020 16:02:00



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:30
User entered '98.9' F	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:34
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:38
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:42
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:04
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:10
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:14
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:55
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:47:36
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:48:00
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:03
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:08
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:11
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:20
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:22
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:30
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:48:32
User entered 'None (None)'	Shelby Pickle (b) (4)	29 Sep 2020 16:02:00

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 8 (Day 8)'	(b) (4)	
	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:25
User entered '30 Sep 2020'	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:39
User entered '0'	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:41
User entered '95'	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:50:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Sep 2020 22:43:29
User entered '101' F reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:43:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Sep 2020 22:42:04
User entered '101' (non-conformant).	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:45
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:50
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:50:52
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:51:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:11
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:14
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:16
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:40
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:51:43
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:51:45
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:51:47
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	30 Sep 2020 22:44:18
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:42:04

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 2 (Day 2)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56
	(b) (4)	



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:04
User entered '24 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:14
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:07
User entered '94'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:10
User entered '98.2' F	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:15:28
User closed query 'Please verify is subject was evaluated for Chills' (Site from CRA).		28 Oct 2020 18:15:23
Query 'Please verify is subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:04:21
User opened query 'Please verify is subject was evaluated for Chills' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:07:27
DataPoint Un-verified.		27 Oct 2020 19:04:51
DataPoint Verified.		27 Oct 2020 18:58:12
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:58:56

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:58:15
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:24
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:26
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:28
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:30
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:32
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:34
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:40
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:58:42
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:44
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:45
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:48
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:49
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:58:52
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 14:58:56

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:58:57
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 14:58:56

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 3 (Day 3)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:59:19
User entered '25 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:59:21
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:59:23
User entered '95'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:59:25
User entered '98.3' F	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:17:11
User closed query 'Please verify if subject was evaluated for Chills' (Site from CRA).		28 Oct 2020 18:15:49
Query 'Please verify if subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:04:31
User opened query 'Please verify if subject was evaluated for Chills' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:08:16
DataPoint Un-verified.		27 Oct 2020 19:01:18
DataPoint Verified.		27 Oct 2020 18:59:27
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:59:29
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:00:07
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:00:10
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:01:56
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:01:58
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:02:01
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:02:32
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:02:37
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:00
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:19
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:23
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:34
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:39
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:43
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:03:46
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:00:38

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 4 (Day 4)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:09:30
User entered '26 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:33
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:36
User entered '94'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:02:10



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:39
User entered '98.0' F	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:35
User closed query 'Please confirm if subject was evaluated for Chills' (Site from CRA).		28 Oct 2020 18:17:30
Query 'Please confirm if subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:04:43
	(b) (4)	
User opened query 'Please confirm if subject was evaluated for Chills' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:11:08
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:14
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:16
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:19
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:21
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:23
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:26
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:32
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:47
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:49
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:11:59
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:12:02
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:12:03
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:12:08
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:12:15
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:12:17
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:10

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 5 (Day 5)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered '27 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered 'I'	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered empty.	System	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:02:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:02:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 6 (Day 6)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16
	(b) (4)	



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:39:30
User entered '28 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:18:02
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:39:35
User entered '94'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:39:37
User entered '99.0' F	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:18:21
User closed query 'Please verify if subject was evaluated for Chills' (Site from CRA).		28 Oct 2020 18:18:12
Query 'Please verify if subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:05:00
User opened query 'Please verify if subject was evaluated for Chills' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:42:06
DataPoint Un-verified.		27 Oct 2020 19:41:09
DataPoint Verified.		27 Oct 2020 19:39:39
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:39:50
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:39:53
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:39:56
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:40:06
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:16
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:38
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:40
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:51
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:53
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:40:56
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:04:16



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:42:17
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:19
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:21
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:24
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:26
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:04:16

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User closed query 'Please enter Day 8 visit into eDC if this visit took place.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:18:44
Query 'Please enter Day 8 visit into eDC if this visit took place.' answered with 'Day 8 previously entered, see log line above' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:05:27
User opened query 'Please enter Day 8 visit into eDC if this visit took place.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:55:30
User entered 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:40
User entered '29 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:55:40
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:43
User entered '95'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:46
User entered '98.6' F	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please verify is subject was evaluated for Chills' (Site from CRA).	(b) (4)	28 Oct 2020 18:19:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:19:10
Query 'Please verify is subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:05:33
User opened query 'Please verify is subject was evaluated for Chills' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:51:03
		27 Oct 2020 19:42:56
DataPoint Verified.		27 Oct 2020 19:42:51
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:54
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:42:58
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:00
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:01
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:04
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:11
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:07
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:08
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:17
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:19
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:21
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:23
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:25
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:43:27
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:49:36
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:06:05

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 9 (Day 9)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:14
User entered '01 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:16
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:20
User entered '91'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:07:42



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:22
User entered '100.9' F	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:27
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:29
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:31
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:33
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:36
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:38
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:07:42

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:43
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:46
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:49
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:52
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:23
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:25
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:34
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:37
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:39
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:02:42
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:07:42

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 10 (Day 10)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:06
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:02:57
User entered '02 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:09
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:02:59
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	05 Nov 2020 04:16:35
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:03:01
User entered '90'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:09:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:12
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:03:07
User entered '102.3' F	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please verify if subject was evaluated for Chills.' (Site from CRA).	(b) (4)	28 Oct 2020 18:19:51
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:19:48
Query 'Please verify if subject was evaluated for Chills.' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:05:43
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:19
User opened query 'Please verify if subject was evaluated for Chills.' (Site from CRA).		27 Oct 2020 20:04:17
DataPoint Un-verified.		27 Oct 2020 20:03:16
DataPoint Verified.		27 Oct 2020 20:03:13
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:20:18
DataPoint Un-verified.		27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:23
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:09:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:20
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:04:25
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:20:23
DataPoint Un-verified.		27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:27
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:09:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:26
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:29
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:29
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:42
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:20:36
DataPoint Un-verified.		27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:45
User entered 'Mild (Mild)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:09:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:32
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:48
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:39
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:50
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:04:52
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:48
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:04:54
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:20:51
DataPoint Un-verified.		27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:05:03
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:09:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:53
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:05:05
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:05:07
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:20:58
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:05:08
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:02:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 18:21:00
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 22:02:48
DataPoint Verified.		27 Oct 2020 20:05:10
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:09:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 11 (Day 11)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08
	(b) (4)	



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:29
User entered '03 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:32
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:34
User entered '90'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:51
User entered '101.4' F	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:21:22
User closed query 'Please verify if subject was evaluated for Chills.' (Site from CRA).		28 Oct 2020 18:21:18
Query 'Please verify if subject was evaluated for Chills.' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:03:43
User opened query 'Please verify if subject was evaluated for Chills.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:06:59
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:15
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:23
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:25
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:30
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:33
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:49
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:51
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:55
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:58
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:00
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:03
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:10
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:12
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:08:15
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:11:08

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:17
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:11:08

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 12 (Day 12)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered '04 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered 'l'	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered empty.	System	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 23:48:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40
	(b) (4)	



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 23:48:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 15:39:40

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 13 (Day 13)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:11
User entered '05 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:13
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please verify as severity assessment noted that no SpO2% but there are multiple entries on symptom log that meet that criteria. Please review and update severity form accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:21:54
Query 'Please verify as severity assessment noted that no SpO2% but there are multiple entries on symptom log that meet that criteria. Please review and update severity form accordingly.' answered with 'Severity assessment page has been updated' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:01:43
User opened query 'Please verify as severity assessment noted that no SpO2% but there are multiple entries on symptom log that meet that criteria. Please review and update severity form accordingly.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:17:33
Query 'Please verify as severity assessment noted that no SpO2% </=93% was recorded.' canceled (Site from CRA).		27 Oct 2020 22:17:00
User opened query 'Please verify as severity assessment noted that no SpO2% </=93% was recorded.' (Site from CRA).		27 Oct 2020 22:16:53
DataPoint Verified.		27 Oct 2020 20:22:16
User entered '90'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:40:51



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:22:17
User entered '101.0' F	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:22:06
User closed query 'Please verify if subject was evaluated for Chills' (Site from CRA).		28 Oct 2020 18:22:03
Query 'Please verify if subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:02:05
User opened query 'Please verify if subject was evaluated for Chills' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:23:49
DataPoint Un-verified.		27 Oct 2020 20:22:57
DataPoint Verified.		27 Oct 2020 20:22:21
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:23
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:24
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:26
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:28
User entered 'Severe (Severe)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:30
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:33
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:39
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:36
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:44
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:47
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:14
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:15
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:17
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:20
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:22
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:40:51

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	11 Nov 2020 16:53:58
User entered 'Day 14 (Day 14)'	(b) (4)	
	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:07
User entered '06 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:20
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:22
User entered '93'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:25:23
User entered '101.2' F	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please verify is subject was evaluated for Chills' (Site from CRA).	(b) (4)	28 Oct 2020 18:22:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:22:22
Query 'Please verify is subject was evaluated for Chills' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:03:53
User opened query 'Please verify is subject was evaluated for Chills' (Site from CRA).	(b) (4)	27 Oct 2020 20:26:38
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:52
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:35
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:25
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58
	(b) (4)	



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:39
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:25:41
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:43
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:56
User entered 'Severe (Severe)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:41:58
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:03
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:05
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:10
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:13
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:29
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:26
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:31
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:34
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:36
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:42:41
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:41:58

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 21 (Day 21)'	(b) (4) Shelby Pickle (b) (4)	22 Oct 2020 15:43:03



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	27 Oct 2020 20:43:02
User entered '14 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:43:02
	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:06
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:09
User entered '93'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered '%'	System	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:43:23
User entered '98.8' F	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please verify if subject was evaluated for chills.' (Site from CRA).	(b) (4)	28 Oct 2020 18:22:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:22:41
Query 'Please verify if subject was evaluated for chills.' answered with 'Patient confirmed via phone that chills were not experienced. See note on source.' (Site from CRA).	Shelby Pickle (b) (4)	28 Oct 2020 16:04:01
User opened query 'Please verify if subject was evaluated for chills.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:44
		27 Oct 2020 20:45:10
DataPoint Verified.		27 Oct 2020 20:45:08
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:45:49
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:02
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:03
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:06
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:08
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:46:20
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:46:22
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Please make entry as per SD.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 04:15:21
DataPoint Verified.		05 Nov 2020 04:15:16
Query 'Please make entry as per SD.' answered with 'Updated' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:06:16
User entered 'None (None)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 16:06:11
User opened query 'Please make entry as per SD.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:47:16
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:32
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:35
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:36
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:43
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:47:46
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:43:03

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:48
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:50
User entered 'None (None)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:03

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 1 (Day 1)'	(b) (4) Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered '21 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered 'l'	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered empty.	System	10 Nov 2020 23:16:27

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27
	(b) (4)	



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:27

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Day 2 (Day 2)'	(b) (4) Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered '22 Sep 2020'	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered 'l'	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 23:48:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User entered empty.	System	10 Nov 2020 23:16:36



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 23:48:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36



US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:02:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:02:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:48:18
User entered empty.	Shelby Pickle (b) (4)	10 Nov 2020 23:16:36

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 22:56:25
User entered '23 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 22:56:25
	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[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 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:25
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:03

[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 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:25
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		30 Sep 2020 16:45:02
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Information correct. Patient tested positive' (Site from System).	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:03:15
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	29 Sep 2020 16:03:02
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:03:02

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:56:25
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:03

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:25
User entered 'Nasal Swab (Nasal Swab)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:03:02

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:56:25
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[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 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:25
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 22:56:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 22:56:25
	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 22:56:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 22:56:25
	Shelby Pickle (b) (4)	29 Sep 2020 16:03:02
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:02:03**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:11
User entered '1'	System	29 Sep 2020 16:03:02

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Did the subject have Respiratory Rates  \$\geq\$  30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:16
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:19
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:21
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:25
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:29
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:32
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:37
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:47
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:02:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	28 Oct 2020 15:57:00
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:02:55
User entered '01 Oct 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4)	28 Oct 2020 15:57:00
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45
	(b) (4)	

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (14OCT2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:08:26 22 Apr 2021 17:29:38
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (14OCT2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' answered with 'corrected ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:15:42
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 15:15:09
Signature has been broken.	Jill York (b) (4)	21 Apr 2021 15:15:09
User entered '14 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:15:09
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (14OCT2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Ripley Hollister (b) (4)	21 Apr 2021 11:19:55 18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:03:12
User entered '05 Oct 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	28 Oct 2020 15:57:00
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:00
User entered '90' reason for change: Data Entry Error	Shelby Pickle (b) (4)	28 Oct 2020 15:57:00
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:06
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:19
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:21
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:03:23
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	10 Nov 2020 22:56:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 16:04:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:04:57
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	29 Sep 2020 16:04:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 16:04:45
User entered empty.	System	29 Sep 2020 16:04:45
	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45
	(b) (4)	

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

US3142100

Folder: Covid-19 Assessment 23 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:02:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45



**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:56:15
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 16:04:45

**US3142100**

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:29:31
DataPoint Verified.		22 Apr 2021 17:30:01
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Yes (Y)'	(b) (4)	
	Shelby Pickle (b) (4)	25 Sep 2020 15:22:33
	(b) (4)	

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40



US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F602263266 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		16 Apr 2021 05:22:18
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F602263266 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'This sample is not required for this visit and was collected in error. This data will not be entered. ' (Site from DM).	Jill York (b) (4)	13 Apr 2021 16:28:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:47
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F602263266 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:02:43
DataPoint Verified.		28 Oct 2020 15:42:27
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered '14 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:02:17
User entered '20 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:47
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '14 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL Lab Reconciliation: Saliva: Per response, Please confirm if the 25SEP2020 sample was shipped then please provide the Accession number and Tracking number with the shipping date to track the sample in PPD as the sample is still missing in PPD ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:01:47
Query 'Per GCL Lab Reconciliation: Saliva: Per response, Please confirm if the 25SEP2020 sample was shipped then please provide the Accession number and Tracking number with the shipping date to track the sample in PPD as the sample is still missing in PPD ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided. ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:18:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Per response, Please confirm if the 25SEP2020 sample was shipped then please provide the Accession number and Tracking number with the shipping date to track the sample in PPD as the sample is still missing in PPD ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:04:02

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020, 27SEP2020, 29SEP2020, 01OCT2020, 06OCT2020 and 13OCT2020  are recorded under Illness Visit Day 3, 5, 7, 9, 14, 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:04:02
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020, 27SEP2020, 29SEP2020, 01OCT2020, 06OCT2020 and 13OCT2020 are recorded under Illness Visit Day 3, 5, 7, 9, 14, 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Samples collected, lab should have records' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:56:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25SEP2020, 27SEP2020, 29SEP2020, 01OCT2020, 06OCT2020 and 13OCT2020 are recorded under Illness Visit Day 3, 5, 7, 9, 14, 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:37:57
User closed query 'Per GCL Lab Recon: GCL is not reporting receiving any Saliva samples. Please clarify if the samples were shipped.' (Site from DM).		09 Nov 2020 06:51:48
DataPoint Verified.		28 Oct 2020 15:42:29
Query 'Per GCL Lab Recon: GCL is not reporting receiving any Saliva samples. Please clarify if the samples were shipped.' answered with 'Samples processed by site and shipped to the facility' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	26 Oct 2020 18:03:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2242 of 2821

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL is not reporting receiving any Saliva samples. Please clarify if the samples were shipped.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:37:11
User entered '25 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:02:03

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621076068 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Apr 2021 05:36:33
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621076068 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'sample was not collected on day 5' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:18:25
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621076068 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:03:31
DataPoint Verified.		10 Nov 2020 22:55:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:17:37
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '15 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 27SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:03:05
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 27SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided.' (Site from DM).	Meghan York (b) (4)	01 Feb 2021 17:19:02
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 27SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:05:15
DataPoint Verified.		10 Nov 2020 22:55:51
User entered '27 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40



US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:02:03

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F621596772 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Apr 2021 05:37:10
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F621596772 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'no sample was collected on day 7' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:19:28
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F621596772 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:04:11
DataPoint Verified.		10 Nov 2020 22:55:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:19:03
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '16 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:04:06
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided.' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:19:09
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 29SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:05:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:55:51
User entered '29 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:02:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602148390 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Apr 2021 05:37:47
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602148390 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'no sample was collected on Day 9' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:20:58
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602148390 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:04:44
DataPoint Verified.		10 Nov 2020 22:55:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:20:28
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '17 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 01OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:04:23
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 01OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided.' (Site from DM).	Meghan York (b) (4)	01 Feb 2021 17:19:16
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 01OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:05:56
DataPoint Verified.		10 Nov 2020 22:55:51
User entered '01 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:02:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621546604 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Apr 2021 05:38:20
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621546604 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'day 14 sample was not collected ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:23:07
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621546604 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:05:28
DataPoint Verified.		10 Nov 2020 22:55:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:22:29
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '18 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 06OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:05:06
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 06OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided.' (Site from DM).	Meghan York (b) (4)	01 Feb 2021 17:19:22
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 06OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:06:25
DataPoint Verified.		10 Nov 2020 22:55:51
User entered '06 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:48:40
	(b) (4)	



US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:03

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:21:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' ' answered with 'now entered for Illness visit Day 28' (Site from DM).	Meghan York (b) (4) (b) (4)	29 Oct 2020 19:00:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:05:43
User accepted default value 'Day 21 (Day 21)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600624292 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Apr 2021 05:38:56
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600624292 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'sample was not collected on day 21' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:24:31
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:01:10
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:01:10
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600624292 is reported with 20-Oct-20 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample labe and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:05:54
DataPoint Verified.		10 Nov 2020 22:55:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

US3142100

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:37:40
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:24:02
DataPoint Un-verified.	Jill York (b) (4)	26 Mar 2021 16:00:41
User entered '19 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	26 Mar 2021 16:00:41
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 13OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:05:35
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 13OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Sample was shipped. However, tracking number and accession number cannot be provided.' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 17:19:36
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 13OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:06:51
DataPoint Verified.		10 Nov 2020 22:55:51
User entered '13 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	29 Oct 2020 19:00:27
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:39:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:55:51
User entered '20 Oct 2020' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	29 Oct 2020 19:00:27
User entered empty.	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:48:40

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:06
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:19:42

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:08
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 23:19:42



**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[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 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:10
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	29 Sep 2020 23:19:42

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered 'SICKD1'	System	29 Sep 2020 23:19:42

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:37
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:40
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:42
User entered '12:32'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered '23 Sep 2020 12:32'	System	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:48
User entered '74' in	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44
DataPoint set to visible.	(b) (4) System	29 Sep 2020 23:19:42

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:44
User entered '256.1' lb	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44
DataPoint set to visible.	(b) (4) System	29 Sep 2020 23:19:42



**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:50
User entered '98.9' F	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:51
User entered 'Other (Other)'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:37:54
User entered 'Temporal'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:00
User entered '86'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered 'bpm'	System	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:02
User entered '14'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered 'breaths/min'	System	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:06
User entered '115'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:44



**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered 'mmHg'	System	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:38:07
User entered '88'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User entered 'mmHg'	System	29 Sep 2020 23:20:44

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:15
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:51

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:17
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 23:20:51

**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:02:03**

[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 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:27
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:21:00



**US3142100**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:38:29
User entered '23 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 23:21:00

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:27
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:30
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[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 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:32
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered 'SICKD28'	System	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

US3142100

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:52
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:54
User entered '13:59'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57



**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered '20 Oct 2020 13:59'	System	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:59
User entered '74' in	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57
DataPoint set to visible.	(b) (4) System	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:02
User entered '146.4' lb	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57
DataPoint set to visible.	(b) (4) System	22 Oct 2020 15:43:26

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:08
User entered '97.6' F	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:10
User entered 'Other (Other)'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:16
User entered 'Temporal'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:19
User entered '77'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered 'bpm'	System	22 Oct 2020 15:45:57



**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:21
User entered '10'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered 'breaths/min'	System	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:23
User entered '124'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered 'mmHg'	System	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:25
User entered '83'	Shelby Pickle (b) (4)	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User entered 'mmHg'	System	22 Oct 2020 15:45:57

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21



**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:42
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:46:05

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:02:44
User entered '20 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 15:46:05

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:02:03**

[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 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:03:02
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	22 Oct 2020 15:46:15

**US3142100**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:03:07
User entered '20 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:46:15

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:50:30

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:50:30

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:50:30

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 21:50:30



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:26:56

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:26:56

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16

US3142100

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:02:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
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 20:21:21
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 17:25:56
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 17:25:45
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 16:15:55
User entered 'mRNA-1273 (mRNA-1273)'		11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered empty.	System	11 Feb 2021 22:11:39
DataPoint set to visible.	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered empty.	System	11 Feb 2021 22:11:39
DataPoint set to visible.	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User accepted default value 'Pre-Dose (PREDOSE)'		11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '13:52'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '11 Feb 2021 13:52'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'bpm'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'breaths/min'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '138'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '84'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:02:03**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered empty.	System	11 Feb 2021 22:11:39
DataPoint set to visible.	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User accepted default value 'Post-Dose (POSTDOSE)'		11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '15:06'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '11 Feb 2021 15:06'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '77'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'bpm'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'breaths/min'	System	11 Feb 2021 22:11:39



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '129'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '75'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	11 Feb 2021 22:11:39

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:40

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:40

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mRNA-1273'	System	11 Feb 2021 21:54:24
DataPoint set to visible.	System	11 Feb 2021 21:51:16

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:36'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '11 Feb 2021 14:36'	System	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'ONCE'	System	11 Feb 2021 21:54:24

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 21:54:24



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:43

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:43

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:24'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:51:43

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '11 Feb 2021 14:24'	System	11 Feb 2021 21:51:43

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:12

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:12

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:24'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:12

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:02:03**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '11 Feb 2021 14:24'	System	11 Feb 2021 21:52:12



**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:52:19

**US3142100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	11 Feb 2021 21:52:19

**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	23 Feb 2021 22:37:21

US3142100

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 19:50:48
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'LM 'S BEFORE. MADE CONTACT.' (Site from System).	Lisa Jackson (b) (4)	23 Feb 2021 22:40:10
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Feb 2021 22:37:21
User entered '23 Feb 2021'	Lisa Jackson (b) (4)	23 Feb 2021 22:37:21

**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	23 Feb 2021 22:37:21

**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Lisa Jackson (b) (4)	23 Feb 2021 22:37:21

**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	23 Feb 2021 22:40:24

**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	23 Feb 2021 22:40:24



**US3142100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	23 Feb 2021 22:40:24
DataPoint set to visible.	System	23 Feb 2021 22:40:24

US3142100

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'Per GCL Lab Recon: Sample for OL-D29 dated 09Mar2021 is reported in PPD Central lab; however Immunogenicity form appears missing. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 20:16:25
Query 'Per GCL Lab Recon: Sample for OL-D29 dated 09Mar2021 is reported in PPD Central lab; however Immunogenicity form appears missing. Please reconcile.' answered with 'This sample is not required for this visit and was collected in error. This data will not be entered. ' (Site from DM).	Jill York (b) (4)	13 Apr 2021 16:29:10
User opened query 'Per GCL Lab Recon: Sample for OL-D29 dated 09Mar2021 is reported in PPD Central lab; however Immunogenicity form appears missing. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 01:51:09
User entered 'Yes (Y)'		09 Mar 2021 21:46:37

**US3142100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:46:37

**US3142100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:46:37

**US3142100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'OLD29'	System	09 Mar 2021 21:46:37

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User accepted default value 'Pre-Dose (PREDOSE)'		09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38



**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '14:19'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '9 Mar 2021 14:19'	System	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '66'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'bpm'	System	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '10'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38



**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'breaths/min'	System	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '131'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '75'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	09 Mar 2021 21:53:38

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User accepted default value 'Post-Dose (POSTDOSE)'		09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44



**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '15:09'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '9 Mar 2021 15:09'	System	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '65'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'bpm'	System	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '10'	(b) (4), (b) (6)	09 Mar 2021 22:19:44



**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'breaths/min'	System	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '150'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '87'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mmHg'	System	09 Mar 2021 22:19:44

**US3142100**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:21

**US3142100**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:21

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46



**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'mRNA-1273'	System	09 Mar 2021 21:47:46
DataPoint set to visible.	System	23 Feb 2021 22:40:24

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '14:39'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered '9 Mar 2021 14:39'	System	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'ONCE'	System	09 Mar 2021 21:47:46



**US3142100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:02:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 21:47:46

**US3142100**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:47:58

**US3142100**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	09 Mar 2021 21:47:58

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	31 Mar 2021 19:42:19

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '16 Mar 2021'	Lisa Jackson (b) (4)	31 Mar 2021 19:42:19

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	31 Mar 2021 19:42:19

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:02:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Lisa Jackson (b) (4)	31 Mar 2021 19:42:19

**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Mar 2021 20:26:50



**US3142100**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:02:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:49:46
User entered 'I'	System	29 Mar 2021 20:26:50

**US3142100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:04

US3142100

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 05:09:15
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Information provided is correct' (Site from System).	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:14
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Mar 2021 20:27:04
User entered '29 Mar 2021'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:04

**US3142100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:04
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:02:03**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 20:27:04

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '29 Mar 2021'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered '14:15'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:42



**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:15'	System	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '98.9' F	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered 'Other (Other)'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered 'Temporal'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '71'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered '10'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:27:42



**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '128'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '83'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:42
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:02:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:27:42

**US3142100**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered 'No (N)'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:47
	(b) (4)	

**US3142100**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:02:03**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:47

**US3142100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:59

**US3142100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
	(b) (4)	
User entered '29 Mar 2021'	Shelby Pickle (b) (4)	29 Mar 2021 20:27:59
	(b) (4)	



**US3142100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:39:50
User entered '14:21'	Shelby Pickle (b) (4) (b) (4)	29 Mar 2021 20:27:59

**US3142100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:02:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:21'	System	29 Mar 2021 20:27:59

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:02:03**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:36:39
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:15:00

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	28 Oct 2020 15:35:44
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 16:11:12
User entered	System	30 Sep 2020 16:11:05
'USA-US064-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	30 Sep 2020 16:11:05

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:35:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:19:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:19:47
Data point term sent to Coder	System	29 Sep 2020 23:19:05
User entered 'COVID-19'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:35:49
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:35:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:35:56
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:36:00
User entered '21 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Sep 2020 23:18:42
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:42
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Sep 2020 23:18:27
User entered '20:00'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 23:18:42
User entered '21 Sep 2020 20:00'	System	29 Sep 2020 23:18:27

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	06 Jan 2021 19:55:34
	Shelby Pickle (b) (4)	06 Jan 2021 19:55:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Shelby Pickle (b) (4)	06 Jan 2021 19:55:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
DataPoint Verified.	System	06 Jan 2021 19:55:26
	(b) (4), (b) (6)	28 Oct 2020 15:36:08
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 23:18:27
	(b) (4)	

US3142100

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:45:17
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Added' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:55:47
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:55:26
User entered '23 Nov 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:55:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:49:25
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		11 Nov 2020 14:27:17
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Patient has ongoing fatigue. All other symptoms resolved 11oct2020. Please advise.' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 22:48:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:46:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		27 Oct 2020 01:10:04
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		23 Oct 2020 13:03:54

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:02:33
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		15 Oct 2020 13:32:13
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Will provide once available, patient symptomatic at this time.' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	14 Oct 2020 16:30:40
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:28:40
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:36:14
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 23:18:27



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:36:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:36:29
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:40
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:46:41
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User closed query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' (Site from DM).		22 Oct 2020 19:00:22
Query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' answered with 'Patient diagnoses after both doses had already been administered' (Site from DM).	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 15:49:50
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 20:39:55
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' answered with 'done' (Site from Safety).	Jami Wagner (b) (4) (b) (4)	19 Oct 2020 23:36:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	19 Oct 2020 23:36:26
User opened query 'Per MM: Please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject will be diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:08:24

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:28:22
User entered 'None (NONE)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered 'I'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:45:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Resolution updated' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:56:02
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:55:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Shelby Pickle (b) (4) (b) (4)	06 Jan 2021 19:55:26
Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:49:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:27:24
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:27:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Ongoing fatigue' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 22:49:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:47:03
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 01:10:21

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 22:05:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'At day 28 patient still experiencing some symptoms - continued fatigue' (Site from Safety).	Shelby Pickle (b) (4)	22 Oct 2020 15:50:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 13:28:56
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 23:18:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 23:18:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shelby Pickle (b) (4)	29 Sep 2020 23:18:50
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 23:18:27
User entered empty.	Shelby Pickle (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:47:03
User entered empty.	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:12:08
User closed query 'PV Query: Please provide results from blood sample taken for immunologic assessment of SARS-COV-2 infection from 23 Sep 2020.' (Site from Safety).		11 Nov 2020 14:27:28
Query 'PV Query: Please provide results from blood sample taken for immunologic assessment of SARS-COV-2 infection from 23 Sep 2020.' answered with 'Positive results noted' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 22:50:00
DataPoint Un-verified.	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 22:49:50
User entered 'PATIENT BEGAN HAVING MILD SYMPTOMS LATE IN THE DAY ON 21SEP2020, AFTER A SPOUSE HAD RECEIVED A POSITIVE COVID-19 TEST FROM ANOTHER FACILITY. THE PATIENT WAS SEEN ONSITE FOR COVID-19 CONFIRMATION TESTING ON 23SEP2020. The patient tested positive at this visit. THE PATIENT'S SYMPTOMS ARE BEING CLOSELY MONITORED BY THE CRC AND PI FOR ANY SIGNIFICANT CHANGES, SUCH AS WORSENING OR RECOVERY. PATIENT DID NOT VISIT ANY OTHER MEDICAL FACILITY OUTSIDE OF THE RESEARCH SITE. THE PATIENT DID USE MOTRIN/ TYLENOL INTERMITTENTLY FOR FEVER REDUCTION PURPOSES.' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	10 Nov 2020 22:49:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:47:03
User opened query 'PV Query: Please provide results from blood sample taken for immunologic assessment of SARS-COV-2 infection from 23 Sep 2020.' (Site from Safety).		27 Oct 2020 16:11:31

US3142100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 22:05:34
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 'Medication information provided. No medical intervention was prescribed by any physician, OTC used for fever reduction. No surgical treatments.' (Site from Safety).	Shelby Pickle (b) (4)	22 Oct 2020 15:51:51
User entered 'PATIENT BEGAN HAVING MILD SYMPTOMS LATE IN THE DAY ON 21SEP2020, AFTER A SPOUSE HAD RECEIVED A POSITIVE COVID-19 TEST FROM ANOTHER FACILITY. THE PATIENT WAS SEEN ONSITE FOR COVID-19 CONFIRMATION TESTING ON 23SEP2020. THE PATIENT'S SYMPTOMS ARE BEING CLOSELY MONITORED BY THE CRC AND PI FOR ANY SIGNIFICANT CHANGES, SUCH AS WORSENING OR RECOVERY. Patient did not visit any other medical facility outside of the research site. The patient did use Motrin/ Tylenol intermittently for fever reduction purposes.' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 15:51:17
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)	06 Oct 2020 13:29:16



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient began having mild symptoms late in the day on 21Sep2020, after a spouse had received a positive COVID-19 test from another facility. The patient was seen onsite for COVID-19 confirmation testing on 23Sep2020. The patient's symptoms are being closely monitored by the CRC and PI for any significant changes, such as worsening or recovery.'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 23:18:27

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29

US3142100

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Alopecia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 17:12:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 17:12:52
Data point term sent to Coder	System	16 Mar 2021 17:12:02
User entered 'Alopecia'	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '01 Dec 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
User entered empty.	System	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '01 Mar 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
User entered empty.	System	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'None (NONE)'	(b) (4)	
	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'l'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26



**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered '0'	(b) (4)	
	Shelby Pickle (b) (4)	16 Mar 2021 17:11:26
	(b) (4)	

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
DataPoint Verified.		22 Apr 2021 15:43:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User entered 'Patient experienced mild but noticeable alopecia post COVID-19 diagnosis.'	(b) (4) Shelby Pickle (b) (4)	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
User entered '0'	System	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29
User entered '0'	System	16 Mar 2021 17:11:26

**US3142100**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:29

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:02:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:48:22
User closed query 'Per ETRTR: Please add medication dosed for COVID-19, if no medication was dosed, please state so within AE CRF, thanks.' (Site from CRA).		23 Oct 2020 15:41:29
Query 'Per ETRTR: Please add medication dosed for COVID-19, if no medication was dosed, please state so within AE CRF, thanks.' answered with 'Site to provide.' (Site from CRA).	Shelby Pickle (b) (4) (b) (4)	14 Oct 2020 16:30:05
User opened query 'Per ETRTR: Please add medication dosed for COVID-19, if no medication was dosed, please state so within AE CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Oct 2020 13:56:17
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:14



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:47:52
Data point term sent to Coder User entered 'Amlodipine'	System Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:15 08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:15
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:17
User entered 'Hypertension'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:26
User entered '10'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:28
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:34
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:36
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:42
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:44
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:15:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:46:47
User entered 'UN UNK 2015'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:16:42
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:16:44
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:16:48
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:16:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:47



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:47

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:46:47

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:17:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:48:52
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Aug 2020 20:48:52
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Aug 2020 20:48:17
User entered 'Atorvastatin'	Shelby Pickle (b) (4)	08 Aug 2020 20:47:27
	(b) (4)	

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:03
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:05
User entered 'Hypercholesterolemia'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:07
User entered '20'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:10
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:13
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:20
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:22
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:25
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:27
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:17:33
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:47:27
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:03
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:05
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:08
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:13
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:47:27

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:47:27

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:48:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:48:52
Data point term sent to Coder	System	08 Aug 2020 20:48:15
User entered 'Allopurinol'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:26
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:28
User entered 'Gout'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:30
User entered '300'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:36
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:39
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:41
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:44
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:46
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:49
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:48:02
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:18:59
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:19
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:21
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:24
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:48:02

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:48:02

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:33
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:34:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:34:15
Data point term sent to Coder	System	08 Aug 2020 20:49:18
User entered 'Restasis Eye Drops'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:35
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:37
User entered 'Chronic Dry Eye'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:40
User entered '2'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:42
User entered 'Other (OTHER)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:48
User entered 'Drops'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:51
User entered 'twice daily (BID)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:53
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:59
User entered 'Intraocular (INTRAOCULAR)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:19:56
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:48:57
User entered 'UN UNK 2018'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:17
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:19
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:21
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:26
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:48:57

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:48:57



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:20:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:50:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:50:53
Data point term sent to Coder	System	08 Aug 2020 20:50:18
User entered 'Vitamin D'	Shelby Pickle (b) (4)	08 Aug 2020 20:49:40
	(b) (4)	

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:37
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:39
User entered 'Vitamin D Deficiency'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:41
User entered '2000'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:44
User entered 'IU (IU)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:46
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:51
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:53
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:55
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:20:58
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:21:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4)	08 Aug 2020 20:49:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:49:40
User entered 'UN UNK 2019'	Shelby Pickle (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:09
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:15
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:17
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:49:40



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:49:40

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:49:40

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 17:21:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:50:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:50:52
Data point term sent to Coder	System	08 Aug 2020 20:50:18
User entered 'Aspirin'	Shelby Pickle (b) (4)	08 Aug 2020 20:50:16
	(b) (4)	

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:29
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:31
User entered 'Heart Health'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:33
User entered '81'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:35
User entered 'mg (mg)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:41
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:43
User entered 'once daily (QD)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:45
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:47
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:49
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 12:57:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per IM all reportable' (Site from System).	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	08 Aug 2020 20:50:16
User entered 'UN UNK 2010'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:21:58
User entered '0'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:22:00
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:22:02
User entered empty.	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:22:04
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:50:16

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:50:16

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4)	27 Oct 2020 17:23:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 09:33:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 09:33:29
Data point term sent to Coder	System	22 Oct 2020 16:26:45
User entered 'Motrin'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44
	(b) (4)	

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:41
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:52:01
' (Site from DM). Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf.	Meghan York (b) (4) (b) (4)	10 Nov 2020 22:22:45
' answered with 'This is not a solicited event. Subject was diagnosed with Covid 19 and took medication to treat fever ' (Site from DM). User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf.	(b) (4), (b) (6)	06 Nov 2020 11:04:45
' (Site from DM). DataPoint Verified.		27 Oct 2020 17:23:43
User entered 'Fever Reduction - COVID 19'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:46
User entered '200'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:48
User entered 'mg (mg)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:50
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:53
User entered 'as needed (PRN)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:23:59
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:01
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:03
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:06
User entered '27 Sep 2020'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:11
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:14
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:19
User entered '10 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:25
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User entered empty.	System	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User entered empty.	System	22 Oct 2020 16:26:44

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:17:13
User entered empty.	System	22 Oct 2020 16:26:44

US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:24:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:28:36
Data point term sent to Coder	System	22 Oct 2020 16:27:46
User entered 'Tylenol'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:35
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32



US3142100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:52:15
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'This is not a solicited event. Subject was diagnosed with Covid 19 and took medication to treat fever' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 22:22:55
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:04:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:37
User entered 'Fever Reduction - COVID 19'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:39
User entered '500'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:41
User entered 'mg (mg)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:43
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:49
User entered 'as needed (PRN)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:51
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:53
User entered 'Oral (ORAL)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:24:55
User entered empty.	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32



**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:00
User entered '05 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:02
User entered '0'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:05
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:12
User entered '10 Oct 2020'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:25:14
User entered 'No (N)'	Shelby Pickle (b) (4)	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User entered empty.	System	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User entered empty.	System	22 Oct 2020 16:27:32

**US3142100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:02:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:12
User entered empty.	System	22 Oct 2020 16:27:32



**US3142100**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:02:03**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:28
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 20:33:58
	(b) (4)	

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'		30 Sep 2020 16:11:05
	System	

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'		30 Sep 2020 16:11:05
	System	

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
User entered '30/Sep/2020 16:11'	System	30 Sep 2020 16:11:43



US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'I'		30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
User entered '15/Oct/2020 09:32'	System	15 Oct 2020 13:32:37

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4)	09 Nov 2020 17:30:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 20:40:09
User entered '1'		15 Oct 2020 13:32:37

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
User entered '20/Oct/2020 20:40'	System	20 Oct 2020 20:40:19

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '1'		20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
User entered '23/Oct/2020 22:08'	System	23 Oct 2020 22:08:37

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:30:04
Reviewed for Safety.		23 Oct 2020 22:08:41
User entered '1'		23 Oct 2020 22:08:37

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:11:57
User entered '11/Nov/2020 14:43'	System	11 Nov 2020 14:43:38

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:45:32
DataPoint Verified.		23 Nov 2020 20:11:57
User entered 'I'		11 Nov 2020 14:43:38

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:24
Query 'Please add report to source documents' canceled (Site from CRA).		28 Oct 2020 13:19:00
User opened query 'Please add report to source documents' (Site from CRA).		27 Oct 2020 21:10:52
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'USA-US064-2020-MRNA-1273-P301000002'		30 Sep 2020 16:11:05
	System	

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:25
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:27
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:30
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:31
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:33
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:36
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:38
Reviewed for Safety.		30 Sep 2020 16:11:35
User entered 'No (N)'	System	30 Sep 2020 16:11:05

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:40
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Ripley'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:42
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Hollister'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:50
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '4190 East Woodmen Road Suite 210'	System	20 Oct 2020 20:40:19



**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:46
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered 'Colorado Springs'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:48
Reviewed for Safety.		23 Oct 2020 22:07:30
User entered '80920'	System	20 Oct 2020 20:40:19

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:34:57
Reviewed for Safety.		15 Oct 2020 13:32:25
User entered 'US'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:02:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	07 Jan 2021 19:45:41
User entered '5'	System	11 Nov 2020 14:43:38
User entered '4'	System	23 Oct 2020 22:08:37
User entered '3'	System	20 Oct 2020 20:40:19
User entered '2'	System	15 Oct 2020 13:32:37
User entered '1'	System	30 Sep 2020 16:11:43

**US3142100**

**Folder: SAE USA-US064-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 11 Aug 2021 22:02:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered '07/Jan/2021 19:45'	(b) (4) System	07 Jan 2021 19:45:41

US3142100

Folder: SAE USA-US064-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:02:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:46:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:39:50
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 19:45:41