

US3142252 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:20:38

All time stamps listed in this document are displayed in GMT

US3142252

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Participant ID

US3142252

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

US3142252

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Date of Birth (MMM yyyy)	(b) (6)	1962
Age		57
Age Units		YEARS
Age (Derived)		57
Sex	Female	<input checked="" type="radio"/>
	Male	<input type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 21:18:52

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Date of Informed Consent (<i>dd MMM yyyy</i>)	25 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 type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 21:18:52

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 21:18:53

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Condition	BILATERAL NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Condition	POSTNASAL DRIP
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142252

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Condition	INTERMIT TEND MOUTH SORES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 16:05
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	132.0 lb
BMI (<i>xxx.x</i>)	22.01188 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Apr 2021 21:18:52

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Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:18:53

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:18:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 108445

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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)	25 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 16:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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)	25 AUG 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 17:12
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 17:12 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 17:12

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	16:18 (24 HR)
Collection date and time (derived)	25 AUG 2020 16:18

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:22	25 AUG 2020 16:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 17:46

PC Open Date & Time

25 AUG 2020 17:32

PC Close Date & Time

25 AUG 2020 20:02

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °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	26 AUG 2020 10:30
PC Open Date & Time	25 AUG 2020 20:57
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

27 AUG 2020 10:39

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

97.7 °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

28 AUG 2020 09:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:05

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 09:59

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 10:30

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 06:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

25 AUG 2020 17:46

PC Open Date & Time

25 AUG 2020 17:32

PC Close Date & Time

25 AUG 2020 20:02

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

2

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

26 AUG 2020 10:32

PC Open Date & Time

25 AUG 2020 20:57

PC Close Date & Time

26 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

27 AUG 2020 10:39

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

28 AUG 2020 09:36

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

28 AUG 2020 12:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 10:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

31 AUG 2020 10:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

01 SEP 2020 06:26

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 17:47
PC Open Date & Time	25 AUG 2020 17:32
PC Close Date & Time	25 AUG 2020 20:02

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 10:33
PC Open Date & Time	25 AUG 2020 20:57
PC Close Date & Time	26 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 10:41
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 09:37
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:07
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 10:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2632

EAB) (1725)

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 10:31
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

59 of 2632

EAB) (1725)

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 06:26
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3142252

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:32:33

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:33

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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)	22 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:15
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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)	22 SEP 2020
Time of assessment (00:00-23:59)	17:04 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3142252

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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) 22 SEP 2020

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

Treatment Date and Time (derived) 22 SEP 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

US3142252

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	15:31 (24 HR)
Collection date and time (derived)	22 SEP 2020 15:31

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:26	22 SEP 2020 15:26
Nasopharyngeal Swab 2	No		

US3142252

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

22 SEP 2020 17:07

PC Open Date & Time

22 SEP 2020 16:54

PC Close Date & Time

22 SEP 2020 19:24

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	23 SEP 2020 10:39
PC Open Date & Time	22 SEP 2020 20:19
PC Close Date & Time	23 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

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

PC Time Stamp 24 SEP 2020 08:45

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

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

PC Time Stamp 25 SEP 2020 14:03

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:07

PC Open Date & Time

22 SEP 2020 16:54

PC Close Date & Time

22 SEP 2020 19:24

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

23 SEP 2020 10:39

PC Open Date & Time

22 SEP 2020 20:19

PC Close Date & Time

23 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

24 SEP 2020 08:45

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

25 SEP 2020 14:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

27 SEP 2020 12:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 17:08
PC Open Date & Time	22 SEP 2020 16:54
PC Close Date & Time	22 SEP 2020 19:24

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:40
PC Open Date & Time	22 SEP 2020 20:19
PC Close Date & Time	23 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 08:46
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 14:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:03
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3142252

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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)	15:24 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 15:24
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142252

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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.

US3142252

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	20 OCT 2020 15:35

US3142252

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 11:59:54
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 06:13:34

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 03:15:48
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 18:40:12

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 17:33:08

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

19 DEC 2020 12:02:00

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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	26 DEC 2020 14:16:32
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

31 DEC 2020 02:12:52

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 10:59:58

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 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 JAN 2021 17:40:54
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

28 JAN 2021 07:16:58

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 05:50:07
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

11 FEB 2021 19:46:47

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 15:56:09
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

28 FEB 2021 19:01:08

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 05:50:12
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 05:39:12

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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 MAR 2021 08:16:21
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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="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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	10 FEB 2022 00:01
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Patient Cloud Close Date & Time	14 FEB 2022 23:59
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US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 SEP 2022 00:01
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 <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"/>

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3142252

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:20:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	28 FEB 2021 19:01:44

US3142252

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:32:33

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments SUBJECT HAS ALREADY BEEN
IN FOR A SICK VISIT

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:33

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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) _____

US3142252

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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.

US3142252

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:18:53

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Date of Contact	11 NOV 2020
Time of Contact	10:32
Date and Time of Contact (derived)	11 NOV 2020 10:32
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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	07 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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

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Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input 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"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.8 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (11)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:39:28

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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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:39:28

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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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:39:28

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 09 Jun 2021 15:20:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	97.0 F
-------------	--------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

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 checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Date of Visit	11 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	11 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 11 NOV 2020

End Date 11 NOV 2020

Oxygen Saturation 90 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 14:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 NOV 2020

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 16:50
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

13 OCT 2020

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	17 DEC 2020 11:19
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 DEC 2020

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

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 DEC 2020

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID SICKD28

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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) _____

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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.

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3142252

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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

Visit date (dd MMM yyyy)	11 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	UNBLND_DECIDE
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US3142252

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 MAR 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 MAR 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

US3142252

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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

US3142252

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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 MAR 2021
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 11:03
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3142252

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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 MAR 2021
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 11:54
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3142252

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3142252

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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 MAR 2021

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

Treatment Date and Time (derived) 11 MAR 2021 11:24

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

US3142252

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	11:03 (24 HR)
Collection date and time (derived)	11 MAR 2021 11:03

US3142252

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00 - 23:59)	11:16
Collection Date and Time (derived)	11 MAR 2021 11:16

US3142252

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:18:52

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142252

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:33

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 APR 2021

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

US3142252

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

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

SUBJECT DECLINED DUE TO SOLICITED ADVERSE EVENTS (NOT AES DUE TO NOT LASTING LONGER THAN 7 DAYS POST DOSE)

What was the study treatment? (Unblinded) _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3142252

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142252

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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 _____

US3142252

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142252

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

AEID	USA-US064-2020-MRNA-1273-P30 1000006
Adverse event	COVID-19 INFECTION
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)	7 NOV 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)	01 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input 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	

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

SUBJECT BECAME
SYMPTOMATIC FOR COVID-19
07NOV2020. SUBJECT
OBTAINED COVID-19 TESTING
09NOV2020 (NOT AT SITE).
SUBJECT CONTACTED SITE
11NOV2020 TO INFORM SITE
THAT HER COVID-19 TEST
CAME BACK POSITIVE.
SUBJECT CAME TO SITE IN THE
AFTERNOON OF 11NOV2020
FOR AN ILLNESS VISIT. ALL
STUDY PROCEDURES
COMPLETED FOR ILLNESS
VISIT. SUBJECT'S STUDY
COVID-19 TEST CAME BACK
POSITIVE. SUBJECT REMAINS
SYMPTOMATIC AT THE TIME
OF THIS DATA ENTRY.

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)	

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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

Yes ☒

No ☐

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

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AFTER SECOND
VACCINATION (LOCATION AND
TYPE OF PAIN UNKNOWN)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 12.5

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

	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 1984
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"/>

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication 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

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EAB) (1725)

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 250

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

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EAB) (1725)

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication HYDROXYCHLOROQUINE

Prophylaxis Yes ☐
No ☒

Indication 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

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EAB) (1725)

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF WRINKLES IN
THE FOREHEAD AND BETWEEN
THE EYEBROWS

Dose per administration 20-30

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify SUBJECT STATED SEVERAL
TIMES A YEAR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:45:22

Generated On: 09 Jun 2021 15:20:38

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTED INTO THE FOREHEAD AND BETWEEN THE EYEBROWS	
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN UNK 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3142252

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 21:39:28

Generated On: 09 Jun 2021 15:20:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3142252

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:20:38

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

US3142252

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

SAEID	USA-US064-2020-MRNA-1273-P301000006
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)	2

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

SAEID	USA-US064-2020-MRNA-1273-P301000006
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)	2
Date of submission (Pre-filled from custom function)	25/NOV/2020 08:47
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

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 21:39:29

Generated On: 09 Jun 2021 15:20:38

SAEID	USA-US064-2020-MRNA-1273-P301000006
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)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 12:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142252 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142252

Form: Participant Creation

Generated On: 09 Jun 2021 15:20:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:23:15
User entered 'US3142252'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:39:15

US3142252

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4)	12 Nov 2020 16:48:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:48:49
DataPoint Verified.		12 Nov 2020 16:41:46
User closed query 'Per CDM: Please complete this form' (Site from DM).		27 Oct 2020 12:40:06
Query 'Per CDM: Please complete this form' answered with 'done' (Site from DM).	Meghan York (b) (4)	21 Oct 2020 19:34:09
User entered 'Yes (Y)'	(b) (4)	21 Oct 2020 19:34:02
User opened query 'Per CDM: Please complete this form' (Site from DM).	Meghan York (b) (4)	27 Sep 2020 10:28:59
	(b) (4), (b) (6)	

US3142252

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:48:55
DataPoint Un-verified.		12 Nov 2020 16:48:52
DataPoint Verified.		12 Nov 2020 16:41:46
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:39:16

US3142252

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:41:46
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	21 Oct 2020 19:34:02

US3142252

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'SCRN'	System	21 Oct 2020 19:34:02

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:49:22
User closed query 'Per CDM: Data is required. Please complete this form' (Site from DM).		28 Oct 2020 14:43:49
Query 'Per CDM: Data is required. Please complete this form' answered with 'complete ' (Site from DM).	Meghan York (b) (4)	23 Oct 2020 16:44:16
User opened query 'Per CDM: Data is required. Please complete this form' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:57:36
User entered '(b) (6)1962'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:39:17

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:46
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	23 Oct 2020 16:44:08
User entered '57' reason for change: Data Entry Error	Meghan York (b) (4)	23 Oct 2020 16:44:08
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	23 Oct 2020 16:43:57
User entered '58'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'YEARS'	System	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '57'	System	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered 'Female (F)'	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered 'l'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:53:48
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:43:57

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered '25 Aug 2020'	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Aug 2020'	System	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '2020'	System	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered 'Amendment 3 (3)'	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered empty.	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered empty.	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered 'No (N)'	Shelby Pickle (b) (4)	25 Aug 2020 23:44:30

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:33:32
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:39:16

US3142252

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'I'	System	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:20:38

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:55:12
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:20:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:55:27
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:48:26

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:16
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)	21 Oct 2020 20:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:50:39
Data point term sent to Coder	System	21 Oct 2020 20:50:18
User entered 'bilateral nearsighted'	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:16
User entered 'un UNK 1974'	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:57:16
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:16
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:16
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:16
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 1974'	System	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '1974'	System	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:49:15

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Ringing in ears - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:50:38
Data point term sent to Coder	System	21 Oct 2020 20:50:18
User entered 'bilateral ringing in ears'	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un Jan 2020'	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 2020'	System	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '2020'	System	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:49:57

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:51:40
Data point term sent to Coder	System	21 Oct 2020 20:51:20
User entered 'postnasal drip'	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un UNK 1985'	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 1985'	System	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '1985'	System	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:50:38

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:51:40
Data point term sent to Coder	System	21 Oct 2020 20:51:20
User entered 'seasonal allergies'	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un Jan 2020'	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 2020'	System	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '2020'	System	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:51:02

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Stomatitis, LLT: Sores mouth - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 10:17:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 10:17:44
Data point term sent to Coder	System	23 Oct 2020 16:45:17
Coding entries removed.	Meghan York (b) (4)	23 Oct 2020 16:45:02
User entered 'intermittent MOUTH SORES' reason for change: Data Entry Error	Meghan York (b) (4)	23 Oct 2020 16:45:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Stomatitis, LLT: Sores mouth - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:53:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:53:43
Data point term sent to Coder	System	21 Oct 2020 20:52:23
User entered 'mouth sores'	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un UNK 1972'	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 16:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 16:44:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4)	23 Oct 2020 16:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:51:29
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 1972'	System	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '1972'	System	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:51:29

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:53:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:53:42
Data point term sent to Coder	System	21 Oct 2020 20:52:24
User entered 'hypothyroidism'	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un UNK 1984'	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 1984'	System	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '1984'	System	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:52:09

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:54:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:54:45
Data point term sent to Coder	System	21 Oct 2020 20:53:27
User entered 'menopause'	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'un UNK 2015'	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:57:41
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'Jan 2015'	System	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '2015'	System	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered empty.	System	21 Oct 2020 20:52:37

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:01:44
User closed query 'Per CDM: Please complete this form as well as PHYSICAL EXAMINATION, MEDICAL HISTORY, and, RISK OF EXPOSURE' (Site from DM).		27 Oct 2020 12:40:31
Query 'Per CDM: Please complete this form as well as PHYSICAL EXAMINATION, MEDICAL HISTORY, and, RISK OF EXPOSURE' answered with 'done' (Site from DM).	Jill York (b) (4)	21 Oct 2020 20:55:11
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:54:54
User opened query 'Per CDM: Please complete this form as well as PHYSICAL EXAMINATION, MEDICAL HISTORY, and, RISK OF EXPOSURE' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 10:30:04

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:49
User entered '25 Aug 2020'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:04
User entered '16:05'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '25 Aug 2020 16:05'	System	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:10
User entered '65' in	Jill York (b) (4)	21 Oct 2020 20:54:54
DataPoint set to visible.	System	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:13
User entered '132.0' lb	Jill York (b) (4)	21 Oct 2020 20:54:54
DataPoint set to visible.	System	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered '22.01188'	System	21 Oct 2020 20:54:54
DataPoint set to visible.	System	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'kg/m2'	System	21 Oct 2020 20:54:54
DataPoint set to visible.	System	25 Aug 2020 23:44:36

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:21
User closed query 'Per CDM: Response noted. However, per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required' (Site from DM).		10 Nov 2020 03:41:36
Query 'Per CDM: Response noted. However, per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required' answered with 'done' (Site from DM).	Meghan York (b) (4)	03 Nov 2020 22:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Nov 2020 22:25:51
User opened query 'Per CDM: Response noted. However, per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:19:09
User entered '98.5' F	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:23
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered 'Other (Other)'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:25
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered 'temporal'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered '67'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'bpm'	System	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered '14'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'breaths/min'	System	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered '118'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'mmHg'	System	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	03 Nov 2020 22:25:51
User entered '78'	Jill York (b) (4)	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User entered 'mmHg'	System	21 Oct 2020 20:54:54

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11

US3142252

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11

US3142252

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:50
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:55:23

US3142252

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:02:50
User entered '25 Aug 2020'	Jill York (b) (4)	21 Oct 2020 20:55:23

US3142252

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered '25 Aug 2020'	Meghan York (b) (4)	23 Oct 2020 16:45:54

US3142252

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered 'No (N)'	Meghan York (b) (4)	23 Oct 2020 16:45:54

US3142252

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4)	12 Nov 2020 17:03:20
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	23 Oct 2020 16:46:14
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	23 Oct 2020 16:45:54
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Meghan York (b) (4)	23 Oct 2020 16:45:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered empty.	Meghan York (b) (4)	23 Oct 2020 16:45:54

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	23 Oct 2020 16:46:14
User entered 'un UNK 2015'	Meghan York (b) (4)	23 Oct 2020 16:45:54

US3142252

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:45:54

US3142252

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	23 Oct 2020 16:46:14
User entered 'un UNK 2015' reason for change: Data Entry Error	Meghan York (b) (4)	23 Oct 2020 16:46:14
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	(b) (4)	23 Oct 2020 16:45:54
User entered empty.	System	23 Oct 2020 16:45:54
	Meghan York (b) (4)	23 Oct 2020 16:45:54
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:03:20
User entered '0'	Meghan York (b) (4)	23 Oct 2020 16:45:54

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'No (N)'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:55:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered 'I'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '0'	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:11
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:04:00
User entered empty.	Jill York (b) (4)	21 Oct 2020 20:55:57

US3142252

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:05:21
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:57:26

US3142252

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:05:21
User entered '25 Aug 2020'	Jill York (b) (4)	22 Sep 2020 22:57:26

US3142252

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:05:21
User entered 'Clinic (Clinic)'	Jill York (b) (4)	22 Sep 2020 22:57:26

US3142252

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'VISIT1'	System	22 Sep 2020 22:57:26

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:44:18

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered '108445'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:44:18

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 22:44:18

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).		24 Sep 2020 15:08:59
Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'done' (Site from DM).	Jill York (b) (4)	22 Sep 2020 22:59:56
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27
User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:47:49

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27

US3142252

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:06:35
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:59:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:57:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:57:29

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '25 Aug 2020'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '16:05'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered '25 Aug 2020 16:05'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '98.5' F	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'Other (Other)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'temporal'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '67'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'bpm'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '14'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'breaths/min'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '118'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'mmHg'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '78'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'mmHg'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered missing code ND - Not Done.	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:07:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 20:59:00
User entered '25 Aug 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Oct 2020 20:59:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 20:58:43
User entered '26 Aug 2020'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '17:12'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered '25 Aug 2020 17:12'	System	21 Oct 2020 20:59:00
User entered '26 Aug 2020 17:12'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '98.1' F	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'Other (Other)'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered 'temporal'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '69'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'bpm'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '14'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'breaths/min'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '140'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'mmHg'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:07:36
User entered '85'	Jill York (b) (4)	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'mmHg'	System	21 Oct 2020 20:58:43

US3142252

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:06:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Meghan York (b) (4)	29 Sep 2020 15:24:22
User entered 'Yes (Y)'	(b) (4)	
	Jill York (b) (4)	22 Sep 2020 22:57:41

US3142252

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:06:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	29 Sep 2020 15:24:22
	(b) (4)	
User entered '25 Aug 2020'	Jill York (b) (4)	22 Sep 2020 22:57:41

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User closed query 'Per CDM: Please complete VITAL SIGNS - DOSING as subject was dosed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:45:44
Query 'Per CDM: Please complete VITAL SIGNS - DOSING as subject was dosed.' answered with 'complete' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 16:47:28
User opened query 'Per CDM: Please complete VITAL SIGNS - DOSING as subject was dosed.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 10:31:29
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	25 Aug 2020 23:45:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Shelby Pickle (b) (4)	25 Aug 2020 23:45:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Aug 2020 23:45:00

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '25 Aug 2020'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '17:12'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered '25 Aug 2020 17:12'	System	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
DataPoint Verified.		19 Apr 2021 23:05:44
User entered 'ONCE'	System	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 23:45:00

US3142252

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:36:30
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:58:29

US3142252

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:36:30
User entered '25 Aug 2020'	Jill York (b) (4)	22 Sep 2020 22:58:29

US3142252

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:36:30
User entered '16:18'	Jill York (b) (4)	22 Sep 2020 22:58:29

US3142252

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered '25 Aug 2020 16:18'	System	22 Sep 2020 22:58:29

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:34:55
User entered '25 Aug 2020'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:55
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:34:55
User entered '16:22'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered '25 Aug 2020 16:22'	System	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:34:55
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:55
User entered empty.	Jill York (b) (4)	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered empty.	System	22 Sep 2020 22:58:49

US3142252

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:35:04
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:54:31

US3142252

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:52
User entered 'I'	System	22 Sep 2020 22:54:31

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:45:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f65b35e-8267-4b53-a145-c319a150f495' User entered 'Yes (Y)'	System	25 Aug 2020 23:46:07
	System	25 Aug 2020 23:46:07

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:45:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f65b35e-8267-4b53-a145-c319a150f495' User entered '98.1'	System	25 Aug 2020 23:46:07
	System	25 Aug 2020 23:46:07

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f65b35e-8267-4b53-a145-c319a150f495'	System	25 Aug 2020 23:46:07
User entered 'No (N)'	System	25 Aug 2020 23:46:07

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:04', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f65b35e-8267-4b53-a145-c319a150f495' User entered '25 Aug 2020 17:46'	System	25 Aug 2020 23:46:07
	System	25 Aug 2020 23:46:07

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 17:32'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:02'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ddf81093-6566-42d0-8e0e-4962b96a53c6' User entered 'Yes (Y)'	System	26 Aug 2020 16:30:31
	System	26 Aug 2020 16:30:31

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:16', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ddf81093-6566-42d0-8e0e-4962b96a53c6' User entered '97.7'	System	26 Aug 2020 16:30:31
	System	26 Aug 2020 16:30:31

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ddf81093-6566-42d0-8e0e-4962b96a53c6'	System	26 Aug 2020 16:30:31
User entered 'No (N)'	System	26 Aug 2020 16:30:31

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:26', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ddf81093-6566-42d0-8e0e-4962b96a53c6' User entered '26 Aug 2020 10:30'	System	26 Aug 2020 16:30:31
	System	26 Aug 2020 16:30:31

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:57'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 2'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:12', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1a4d1bd1-8f2b-40d2-99c0-ffd09b7410df' User entered 'Yes (Y)'	System	27 Aug 2020 16:39:33
	System	27 Aug 2020 16:39:33

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:19', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1a4d1bd1-8f2b-40d2-99c0-ffd09b7410df' User entered '98.0'	System	27 Aug 2020 16:39:33
	System	27 Aug 2020 16:39:33

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1a4d1bd1-8f2b-40d2-99c0-ffd09b7410df' User entered 'No (N)'	System	27 Aug 2020 16:39:33
	System	27 Aug 2020 16:39:33

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:29', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1a4d1bd1-8f2b-40d2-99c0-ffd09b7410df' User entered '27 Aug 2020 10:39'	System	27 Aug 2020 16:39:33
	System	27 Aug 2020 16:39:33

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 3'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:35:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '513841c7-2c9e-444c-bae6-d783ba9105df' User entered 'Yes (Y)'	System	28 Aug 2020 15:36:02
	System	28 Aug 2020 15:36:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:35:51', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '513841c7-2c9e-444c-bae6-d783ba9105df' User entered '97.7'	System	28 Aug 2020 15:36:02
	System	28 Aug 2020 15:36:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:35:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '513841c7-2c9e-444c-bae6-d783ba9105df' User entered 'No (N)'	System	28 Aug 2020 15:36:02
	System	28 Aug 2020 15:36:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:35:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '513841c7-2c9e-444c-bae6-d783ba9105df' User entered '28 Aug 2020 09:35'	System	28 Aug 2020 15:36:02
	System	28 Aug 2020 15:36:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 4'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:00:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '78e121e8-417b-41cb-b795-4ea1dd9efe66' User entered 'Yes (Y)'	System	28 Aug 2020 18:06:02
	System	28 Aug 2020 18:06:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:05:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '78e121e8-417b-41cb-b795-4ea1dd9efe66' User entered '98.1'	System	28 Aug 2020 18:06:02
	System	28 Aug 2020 18:06:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:05:55', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '78e121e8-417b-41cb-b795-4ea1dd9efe66'	System	28 Aug 2020 18:06:02
User entered 'No (N)'	System	28 Aug 2020 18:06:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:05:59', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '78e121e8-417b-41cb-b795-4ea1dd9efe66' User entered '28 Aug 2020 12:05'	System	28 Aug 2020 18:06:02
	System	28 Aug 2020 18:06:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 5'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '11fa444a-23ba-4646-a55d-4f1a6562c09e' User entered 'Yes (Y)'	System	30 Aug 2020 15:59:38
	System	30 Aug 2020 15:59:38

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '11fa444a-23ba-4646-a55d-4f1a6562c09e' User entered '97.8'	System	30 Aug 2020 15:59:38
	System	30 Aug 2020 15:59:38

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '11fa444a-23ba-4646-a55d-4f1a6562c09e' User entered 'No (N)'	System	30 Aug 2020 15:59:38
	System	30 Aug 2020 15:59:38

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:34', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '11fa444a-23ba-4646-a55d-4f1a6562c09e' User entered '30 Aug 2020 09:59'	System	30 Aug 2020 15:59:38
	System	30 Aug 2020 15:59:38

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 6'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:30:37', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '356446fb-ae3-424e-8490-cf4c044ec18a' User entered 'Yes (Y)'	System	31 Aug 2020 16:34:57
	System	31 Aug 2020 16:34:57

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:30:45', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '356446fb-ae3-424e-8490-cf4c044ec18a' User entered '98.1'	System	31 Aug 2020 16:34:57
	System	31 Aug 2020 16:34:57

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:30:49', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '356446fb-ae3-424e-8490-cf4c044ec18a' User entered 'No (N)'	System	31 Aug 2020 16:34:57
	System	31 Aug 2020 16:34:57

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:30:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '356446fb-ae3-424e-8490-cf4c044ec18a' User entered '31 Aug 2020 10:30'	System	31 Aug 2020 16:34:57
	System	31 Aug 2020 16:34:57

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 7'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:25:47', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '63173301-8fcf-45d2-89b1-65fa5fecc388' User entered 'Yes (Y)'	System	01 Sep 2020 12:26:02
	System	01 Sep 2020 12:26:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:25:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '63173301-8fcf-45d2-89b1-65fa5fecc388' User entered '97.8'	System	01 Sep 2020 12:26:02
	System	01 Sep 2020 12:26:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:25:56', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '63173301-8fcf-45d2-89b1-65fa5fecc388'	System	01 Sep 2020 12:26:02
User entered 'No (N)'	System	01 Sep 2020 12:26:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:25:59', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '63173301-8fcf-45d2-89b1-65fa5fecc388'	System	01 Sep 2020 12:26:02
User entered '01 Sep 2020 06:25'	System	01 Sep 2020 12:26:02

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:15', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd9b18395-9577-4a37-9696-fdfbd5945ce1' User entered 'None (1)'	System	25 Aug 2020 23:46:51
	System	25 Aug 2020 23:46:51

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd9b18395-9577-4a37-9696-fdfbd5945ce1' User entered 'No (N)'	System	25 Aug 2020 23:46:51
	System	25 Aug 2020 23:46:51

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd9b18395-9577-4a37-9696-fdfbd5945ce1' User entered 'No (N)'	System	25 Aug 2020 23:46:51
	System	25 Aug 2020 23:46:51

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:44', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd9b18395-9577-4a37-9696-fdfbd5945ce1' User entered 'None (1)'	System	25 Aug 2020 23:46:51
	System	25 Aug 2020 23:46:51

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:48', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd9b18395-9577-4a37-9696-fdfbd5945ce1' User entered '25 Aug 2020 17:46'	System	25 Aug 2020 23:46:51
	System	25 Aug 2020 23:46:51

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 17:32'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:02'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:36', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered 'None (1)'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:30:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered 'No (N)'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:31:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered 'Yes (Y)'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:32:18', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered '2'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:32:33', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered 'None (1)'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:32:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '429531de-ba23-40e1-a674-a05809c49d36' User entered '26 Aug 2020 10:32'	System	26 Aug 2020 16:32:42
	System	26 Aug 2020 16:32:42

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:57'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 2'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:37', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '546922eb-90e4-4368-9299-322129ea8848' User entered 'None (1)'	System	27 Aug 2020 16:40:09
	System	27 Aug 2020 16:40:09

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '546922eb-90e4-4368-9299-322129ea8848' User entered 'No (N)'	System	27 Aug 2020 16:40:09
	System	27 Aug 2020 16:40:09

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:42', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '546922eb-90e4-4368-9299-322129ea8848' User entered 'No (N)'	System	27 Aug 2020 16:40:09
	System	27 Aug 2020 16:40:09

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '546922eb-90e4-4368-9299-322129ea8848' User entered 'None (1)'	System	27 Aug 2020 16:40:09
	System	27 Aug 2020 16:40:09

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:39:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '546922eb-90e4-4368-9299-322129ea8848' User entered '27 Aug 2020 10:39'	System	27 Aug 2020 16:40:09
	System	27 Aug 2020 16:40:09

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 3'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:01', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1d5a1726-c5c9-4a40-a37b-dab5a1697cdc' User entered 'None (1)'	System	28 Aug 2020 15:36:27
	System	28 Aug 2020 15:36:27

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:04', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1d5a1726-c5c9-4a40-a37b-dab5a1697cdc' User entered 'No (N)'	System	28 Aug 2020 15:36:27
	System	28 Aug 2020 15:36:27

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1d5a1726-c5c9-4a40-a37b-dab5a1697cdc' User entered 'No (N)'	System	28 Aug 2020 15:36:27
	System	28 Aug 2020 15:36:27

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1d5a1726-c5c9-4a40-a37b-dab5a1697cdc' User entered 'None (1)'	System	28 Aug 2020 15:36:27
	System	28 Aug 2020 15:36:27

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1d5a1726-c5c9-4a40-a37b-dab5a1697cdc' User entered '28 Aug 2020 09:36'	System	28 Aug 2020 15:36:27
	System	28 Aug 2020 15:36:27

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 4'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b7253625-5af5-4d27-9bb0-d372c6298e38'	System	28 Aug 2020 18:06:33
User entered 'None (1)'	System	28 Aug 2020 18:06:33

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:07', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b7253625-5af5-4d27-9bb0-d372c6298e38'	System	28 Aug 2020 18:06:33
User entered 'No (N)'	System	28 Aug 2020 18:06:33

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:10', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b7253625-5af5-4d27-9bb0-d372c6298e38'	System	28 Aug 2020 18:06:33
User entered 'No (N)'	System	28 Aug 2020 18:06:33

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:24', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b7253625-5af5-4d27-9bb0-d372c6298e38'	System	28 Aug 2020 18:06:33
User entered 'None (1)'	System	28 Aug 2020 18:06:33

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b7253625-5af5-4d27-9bb0-d372c6298e38' User entered '28 Aug 2020 12:06'	System	28 Aug 2020 18:06:33
	System	28 Aug 2020 18:06:33

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 5'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '89ce9fa8-e1d1-46fa-9734-e9e0ee7fee86'	System	30 Aug 2020 16:00:12
User entered 'None (1)'	System	30 Aug 2020 16:00:12

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:42', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '89ce9fa8-e1d1-46fa-9734-e9e0ee7fee86'	System	30 Aug 2020 16:00:12
User entered 'No (N)'	System	30 Aug 2020 16:00:12

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T09:59:45', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '89ce9fa8-e1d1-46fa-9734-e9e0ee7fee86' User entered 'No (N)'	System	30 Aug 2020 16:00:12
	System	30 Aug 2020 16:00:12

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '89ce9fa8-e1d1-46fa-9734-e9e0ee7fee86'	System	30 Aug 2020 16:00:12
User entered 'None (1)'	System	30 Aug 2020 16:00:12

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:07', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '89ce9fa8-e1d1-46fa-9734-e9e0ee7fee86' User entered '30 Aug 2020 10:00'	System	30 Aug 2020 16:00:12
	System	30 Aug 2020 16:00:12

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 6'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:30:59', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6f1c749e-47d6-4ac5-8086-64623ee011aa' User entered 'None (1)'	System	31 Aug 2020 16:35:10
	System	31 Aug 2020 16:35:10

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6f1c749e-47d6-4ac5-8086-64623ee011aa' User entered 'No (N)'	System	31 Aug 2020 16:35:10
	System	31 Aug 2020 16:35:10

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6f1c749e-47d6-4ac5-8086-64623ee011aa' User entered 'No (N)'	System	31 Aug 2020 16:35:10
	System	31 Aug 2020 16:35:10

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6f1c749e-47d6-4ac5-8086-64623ee011aa' User entered 'None (1)'	System	31 Aug 2020 16:35:10
	System	31 Aug 2020 16:35:10

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6f1c749e-47d6-4ac5-8086-64623ee011aa' User entered '31 Aug 2020 10:31'	System	31 Aug 2020 16:35:10
	System	31 Aug 2020 16:35:10

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 7'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:03', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '98e27a4f-3ea7-4484-916b-05f83440a25d' User entered 'None (1)'	System	01 Sep 2020 12:26:34
	System	01 Sep 2020 12:26:34

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '98e27a4f-3ea7-4484-916b-05f83440a25d' User entered 'No (N)'	System	01 Sep 2020 12:26:34
	System	01 Sep 2020 12:26:34

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:13', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '98e27a4f-3ea7-4484-916b-05f83440a25d' User entered 'No (N)'	System	01 Sep 2020 12:26:34
	System	01 Sep 2020 12:26:34

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:27', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '98e27a4f-3ea7-4484-916b-05f83440a25d' User entered 'None (1)'	System	01 Sep 2020 12:26:34
	System	01 Sep 2020 12:26:34

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:30', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '98e27a4f-3ea7-4484-916b-05f83440a25d' User entered '01 Sep 2020 06:26'	System	01 Sep 2020 12:26:34
	System	01 Sep 2020 12:26:34

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:46:57', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:09', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:13', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'None (0)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered 'No (N)'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-25T17:47:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3e4812de-cdfe-4882-9cfc-06cce316d25c' User entered '25 Aug 2020 17:47'	System	25 Aug 2020 23:47:26
	System	25 Aug 2020 23:47:26

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 17:32'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:02'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:32:59', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:16', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:26', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:29', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'None (0)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:36', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered 'No (N)'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-26T10:33:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6d262b77-4da5-4434-8ca7-281d18b8688a' User entered '26 Aug 2020 10:33'	System	26 Aug 2020 16:33:42
	System	26 Aug 2020 16:33:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Aug 2020 20:57'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 2'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:03', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'None (0)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:12', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'Some interference with activity (2)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:21', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'No interference with activity (1)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:36', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'None (0)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'None (0)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:42', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'None (0)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:40:46', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered 'No (N)'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-27T10:41:07', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'd0eed59f-9b85-4b29-ab87-c80525128baf' User entered '27 Aug 2020 10:41'	System	27 Aug 2020 16:41:12
	System	27 Aug 2020 16:41:12

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 3'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:29', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788' User entered 'None (0)'	System	28 Aug 2020 15:37:04
	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:33', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788'	System	28 Aug 2020 15:37:04
User entered 'No interference with activity (1)'	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:41', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788'	System	28 Aug 2020 15:37:04
User entered 'No interference with activity (1)'	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:47', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788' User entered 'None (0)'	System	28 Aug 2020 15:37:04
	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788' User entered 'None (0)'	System	28 Aug 2020 15:37:04
	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788' User entered 'None (0)'	System	28 Aug 2020 15:37:04
	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:36:57', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788'	System	28 Aug 2020 15:37:04
User entered 'No (N)'	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T09:37:01', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7cbce2fb-5d6a-43ca-9b08-ac737cf04788' User entered '28 Aug 2020 09:37'	System	28 Aug 2020 15:37:04
	System	28 Aug 2020 15:37:04

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 4'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:35', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered 'None (0)'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d'	System	28 Aug 2020 18:07:08
User entered 'No interference with activity (1)'	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d'	System	28 Aug 2020 18:07:08
User entered 'No interference with activity (1)'	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:55', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered 'None (0)'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:06:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered 'None (0)'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered 'None (0)'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:07:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered 'No (N)'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-28T12:07:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '4c42365f-5d4a-4eaf-aab1-1e31515a167d' User entered '28 Aug 2020 12:07'	System	28 Aug 2020 18:07:08
	System	28 Aug 2020 18:07:08

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 5'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:15', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:25', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:27', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'None (0)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:29', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered 'No (N)'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-30T10:00:32', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '80d6787d-f811-437b-afe9-cf452fa2acb2' User entered '30 Aug 2020 10:00'	System	30 Aug 2020 16:00:42
	System	30 Aug 2020 16:00:42

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 6'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:19', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:25', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:27', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'None (0)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered 'No (N)'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-08-31T10:31:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5b813b6c-351a-416e-8ba2-4bd178d8ef29' User entered '31 Aug 2020 10:31'	System	31 Aug 2020 16:35:19
	System	31 Aug 2020 16:35:19

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 7'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:34', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:37', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:38', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:42', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:44', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'None (0)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:50', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered 'No (N)'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-01T06:26:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '2b7a8daa-e038-4904-8256-56648d7163c8' User entered '01 Sep 2020 06:26'	System	01 Sep 2020 12:26:54
	System	01 Sep 2020 12:26:54

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 23:45:00

US3142252

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:43:41
User entered 'Yes (Y)'	Jill York (b) (4)	23 Sep 2020 19:43:14

US3142252

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:08:16
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		24 Sep 2020 15:08:49
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'no, date is correct' (Site from System).	Jill York (b) (4)	23 Sep 2020 19:43:47
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Sep 2020 19:43:14
User entered '8 Sep 2020'	Jill York (b) (4)	23 Sep 2020 19:43:14

US3142252

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:18
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	23 Sep 2020 19:43:14

US3142252

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:08:19
User entered empty.	Jill York (b) (4)	23 Sep 2020 19:43:14

US3142252

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:27:28
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:54:39

US3142252

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:10:36
User entered 'I'	System	22 Sep 2020 22:54:39

US3142252

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:11:42
User entered 'Yes (Y)'	Jill York (b) (4)	23 Sep 2020 19:44:07

US3142252

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:11:45
User entered '9 Sep 2020'	Jill York (b) (4)	23 Sep 2020 19:44:07

US3142252

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:11:45
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	23 Sep 2020 19:44:07

US3142252

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:11:45
User entered empty.	Jill York (b) (4)	23 Sep 2020 19:44:07

US3142252

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:12:00
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:54:46

US3142252

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:17:58
User entered 'I'	System	22 Sep 2020 22:54:46

US3142252

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:13:17
User entered 'Yes (Y)'	Jill York (b) (4)	23 Sep 2020 19:44:26

US3142252

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:13:17
User entered '15 Sep 2020'	Jill York (b) (4)	23 Sep 2020 19:44:26

US3142252

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:13:17
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	23 Sep 2020 19:44:26

US3142252

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:13:17
User entered empty.	Jill York (b) (4)	23 Sep 2020 19:44:26

US3142252

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:13:27
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:54:53

US3142252

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:29:28
User entered 'I'	System	22 Sep 2020 22:54:53

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for the response, however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 13 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:43:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:32:39
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for the response, however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 13 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' answered with 'illness visit added' (Site from DM).	Jill York (b) (4)	19 Apr 2021 23:14:58
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for the response, however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 13 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 04:28:09
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 13 OCT 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 04:28:09
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 13 OCT 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' answered with 'site to add previous illness visit - subject tested negative at previous illness visit ' (Site from DM).	Jill York (b) (4)	24 Nov 2020 21:42:47

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 13 OCT 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:28:58
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 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).		23 Nov 2020 07:28:58
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 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 'site to add illness visit' (Site from DM).	Jill York (b) (4)	20 Nov 2020 20:27:22
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 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 06:31:30
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:55:05

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:17:27
DataPoint Un-verified.		12 Nov 2020 18:17:16
DataPoint Verified.		12 Nov 2020 17:09:37
User entered '22 Sep 2020'	Jill York (b) (4)	22 Sep 2020 22:55:05

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4)	12 Nov 2020 18:17:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:17:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:09:40
User entered 'Clinic (Clinic)'	Jill York (b) (4)	22 Sep 2020 22:55:05

US3142252

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'VISIT2'	System	22 Sep 2020 22:55:05

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:18:16
DataPoint Un-verified.		12 Nov 2020 18:18:14
DataPoint Verified.		12 Nov 2020 17:14:15
User entered 'Yes (Y)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '22 Sep 2020'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '15:15'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '22 Sep 2020 15:15'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '97.7' F	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered 'Other (Other)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered 'temporal'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '80'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'bpm'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '12'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'breaths/min'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '122'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '78'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered 'Yes (Y)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '22 Sep 2020'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '17:04'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '22 Sep 2020 17:04'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '98.0' F	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered 'Other (Other)'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered 'temporal'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '67'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'bpm'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '12'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'breaths/min'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '135'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:14:15
User entered '89'	Jill York (b) (4)	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	23 Sep 2020 20:18:33

US3142252

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:20:18
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:55:17

US3142252

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:20:18
User entered '22 Sep 2020'	Jill York (b) (4)	22 Sep 2020 22:55:17

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered empty.	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered empty.	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered '22 Sep 2020'	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered '16:34'	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '22 Sep 2020 16:34'	System	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:21:35
User entered 'Left Arm (LEFT ARM)'	Jill York (b) (4)	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
DataPoint Verified.		12 Nov 2020 18:21:35
User entered 'ONCE'	System	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 22:55:34

US3142252

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:23:29
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:55:57

US3142252

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:29:09
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:14:01
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Sample was sent by site, however, tracking number can not be provided ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 19:00:12
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 22SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:51:03
User entered '22 Sep 2020'	Jill York (b) (4)	22 Sep 2020 22:55:57

US3142252

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:23:37
User entered '15:31'	Jill York (b) (4)	22 Sep 2020 22:55:57

US3142252

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '22 Sep 2020 15:31'	System	22 Sep 2020 22:55:57

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:24:19
User entered '22 Sep 2020'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:24:19
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:24:19
User entered '15:26'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '22 Sep 2020 15:26'	System	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:24:19
User entered 'No (N)'	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:24:19
User entered empty.	Jill York (b) (4)	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered empty.	System	22 Sep 2020 22:56:13

US3142252

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:24:34
User entered 'Yes (Y)'	Jill York (b) (4)	22 Sep 2020 22:56:18

US3142252

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '1'	System	22 Sep 2020 22:56:18

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:06:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f01cd614-325c-457f-9b60-3f7efe51398a' User entered 'Yes (Y)'	System	22 Sep 2020 23:07:23
	System	22 Sep 2020 23:07:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f01cd614-325c-457f-9b60-3f7efe51398a' User entered '98.0'	System	22 Sep 2020 23:07:23
	System	22 Sep 2020 23:07:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f01cd614-325c-457f-9b60-3f7efe51398a' User entered 'No (N)'	System	22 Sep 2020 23:07:23
	System	22 Sep 2020 23:07:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:19', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f01cd614-325c-457f-9b60-3f7efe51398a' User entered '22 Sep 2020 17:07'	System	22 Sep 2020 23:07:23
	System	22 Sep 2020 23:07:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 16:54'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 19:24'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'afec6d5d-f3cc-4130-b0c1-60ab6f898ee0' User entered 'Yes (Y)'	System	23 Sep 2020 16:39:39
	System	23 Sep 2020 16:39:39

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'afec6d5d-f3cc-4130-b0c1-60ab6f898ee0' User entered '98.1'	System	23 Sep 2020 16:39:39
	System	23 Sep 2020 16:39:39

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:34', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'afec6d5d-f3cc-4130-b0c1-60ab6f898ee0' User entered 'No (N)'	System	23 Sep 2020 16:39:39
	System	23 Sep 2020 16:39:39

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:37', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'afec6d5d-f3cc-4130-b0c1-60ab6f898ee0' User entered '23 Sep 2020 10:39'	System	23 Sep 2020 16:39:39
	System	23 Sep 2020 16:39:39

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 20:19'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 2'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:44:33', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered 'Yes (Y)'	System	24 Sep 2020 14:45:12
	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:44:48', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered '97.8'	System	24 Sep 2020 14:45:12
	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:44:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered 'Yes (Y)'	System	24 Sep 2020 14:45:12
	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. Medication is now listed on ConMed page.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 02:29:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered '1'	Meghan York (b) (4) (b) (4)	13 Nov 2020 16:39:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Sep 2020 14:45:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered '1'	System	24 Sep 2020 14:45:12
User entered '1'	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered '0'	System	24 Sep 2020 14:45:12
	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:07', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e321db42-ef6e-4851-b94c-79de39402220' User entered '24 Sep 2020 08:45'	System	24 Sep 2020 14:45:12
	System	24 Sep 2020 14:45:12

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 3'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 4'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:12', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170' User entered 'Yes (Y)'	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:21', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170' User entered '98.1'	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170'	System	25 Sep 2020 20:03:54
User entered 'Yes (Y)'	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. Medication is now listed on ConMed page.' (Site from System).	(b) (4)	17 Nov 2020 02:29:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Meghan York (b) (4)	13 Nov 2020 16:39:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170'	(b) (4)	
User entered '1'	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170' User entered '0'	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:50', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '5bc66104-81b7-4af5-ae5d-6e6dbff25170' User entered '25 Sep 2020 14:03'	System	25 Sep 2020 20:03:54
	System	25 Sep 2020 20:03:54

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 5'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 6'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:00:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '68ed675a-ce3e-41b6-9614-8e6afbba4ed7' User entered 'Yes (Y)'	System	27 Sep 2020 18:03:18
	System	27 Sep 2020 18:03:18

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '68ed675a-ce3e-41b6-9614-8e6afbba4ed7' User entered '98.1'	System	27 Sep 2020 18:03:18
	System	27 Sep 2020 18:03:18

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '68ed675a-ce3e-41b6-9614-8e6afbba4ed7' User entered 'No (N)'	System	27 Sep 2020 18:03:18
	System	27 Sep 2020 18:03:18

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:14', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '68ed675a-ce3e-41b6-9614-8e6afbba4ed7' User entered '27 Sep 2020 12:03'	System	27 Sep 2020 18:03:18
	System	27 Sep 2020 18:03:18

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 7'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:32', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ebd9bb45-59ec-41b2-96ad-f6edfc27e936'	System	22 Sep 2020 23:08:03
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 23:08:03

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:41', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ebd9bb45-59ec-41b2-96ad-f6edfc27e936'	System	22 Sep 2020 23:08:03
User entered 'No (N)'	System	22 Sep 2020 23:08:03

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:48', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ebd9bb45-59ec-41b2-96ad-f6edfc27e936'	System	22 Sep 2020 23:08:03
User entered 'No (N)'	System	22 Sep 2020 23:08:03

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ebd9bb45-59ec-41b2-96ad-f6edfc27e936'	System	22 Sep 2020 23:08:03
User entered 'None (1)'	System	22 Sep 2020 23:08:03

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:07:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ebd9bb45-59ec-41b2-96ad-f6edfc27e936'	System	22 Sep 2020 23:08:03
User entered '22 Sep 2020 17:07'	System	22 Sep 2020 23:08:03

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 16:54'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 19:24'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:41', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7bcce7f1-f2e9-4af0-946a-9506fac79297'	System	23 Sep 2020 16:40:01
User entered 'None (1)'	System	23 Sep 2020 16:40:01

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:44', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7bcce7f1-f2e9-4af0-946a-9506fac79297'	System	23 Sep 2020 16:40:01
User entered 'No (N)'	System	23 Sep 2020 16:40:01

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:47', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7bcce7f1-f2e9-4af0-946a-9506fac79297'	System	23 Sep 2020 16:40:01
User entered 'No (N)'	System	23 Sep 2020 16:40:01

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:56', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7bcce7f1-f2e9-4af0-946a-9506fac79297'	System	23 Sep 2020 16:40:01
User entered 'None (1)'	System	23 Sep 2020 16:40:01

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:39:59', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7bcce7f1-f2e9-4af0-946a-9506fac79297'	System	23 Sep 2020 16:40:01
User entered '23 Sep 2020 10:39'	System	23 Sep 2020 16:40:01

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 20:19'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 2'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '03e5ae92-d70c-43c7-a44d-e8bdb60bada9' User entered 'None (1)'	System	24 Sep 2020 14:45:35
	System	24 Sep 2020 14:45:35

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:18', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '03e5ae92-d70c-43c7-a44d-e8bdb60bada9' User entered 'No (N)'	System	24 Sep 2020 14:45:35
	System	24 Sep 2020 14:45:35

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '03e5ae92-d70c-43c7-a44d-e8bdb60bada9' User entered 'No (N)'	System	24 Sep 2020 14:45:35
	System	24 Sep 2020 14:45:35

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '03e5ae92-d70c-43c7-a44d-e8bdb60bada9' User entered 'None (1)'	System	24 Sep 2020 14:45:35
	System	24 Sep 2020 14:45:35

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:45:32', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '03e5ae92-d70c-43c7-a44d-e8bdb60bada9' User entered '24 Sep 2020 08:45'	System	24 Sep 2020 14:45:35
	System	24 Sep 2020 14:45:35

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 3'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 4'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:55', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f364de1e-6061-4339-b7cc-1183ab805dd6' User entered 'None (1)'	System	25 Sep 2020 20:04:09
	System	25 Sep 2020 20:04:09

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:03:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f364de1e-6061-4339-b7cc-1183ab805dd6' User entered 'No (N)'	System	25 Sep 2020 20:04:09
	System	25 Sep 2020 20:04:09

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f364de1e-6061-4339-b7cc-1183ab805dd6' User entered 'No (N)'	System	25 Sep 2020 20:04:09
	System	25 Sep 2020 20:04:09

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:03', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f364de1e-6061-4339-b7cc-1183ab805dd6' User entered 'None (1)'	System	25 Sep 2020 20:04:09
	System	25 Sep 2020 20:04:09

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'f364de1e-6061-4339-b7cc-1183ab805dd6' User entered '25 Sep 2020 14:04'	System	25 Sep 2020 20:04:09
	System	25 Sep 2020 20:04:09

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 5'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 6'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '79681e5a-2c06-4185-b2e8-3d9934a0219d' User entered 'None (1)'	System	27 Sep 2020 18:03:39
	System	27 Sep 2020 18:03:39

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '79681e5a-2c06-4185-b2e8-3d9934a0219d' User entered 'No (N)'	System	27 Sep 2020 18:03:39
	System	27 Sep 2020 18:03:39

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '79681e5a-2c06-4185-b2e8-3d9934a0219d' User entered 'No (N)'	System	27 Sep 2020 18:03:39
	System	27 Sep 2020 18:03:39

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:34', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '79681e5a-2c06-4185-b2e8-3d9934a0219d' User entered 'None (1)'	System	27 Sep 2020 18:03:39
	System	27 Sep 2020 18:03:39

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:37', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '79681e5a-2c06-4185-b2e8-3d9934a0219d' User entered '27 Sep 2020 12:03'	System	27 Sep 2020 18:03:39
	System	27 Sep 2020 18:03:39

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 7'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:11', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:14', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:16', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'None (0)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered 'No (N)'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-22T17:08:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a136cdcd-1dc3-4e61-9d49-9fa99f4271fb' User entered '22 Sep 2020 17:08'	System	22 Sep 2020 23:08:25
	System	22 Sep 2020 23:08:25

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 16:54'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 19:24'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:03', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:06', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:10', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:12', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:14', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'None (0)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered 'No (N)'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-23T10:40:20', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'cf8332d2-5f38-4a69-9f4b-b999c2ebc861' User entered '23 Sep 2020 10:40'	System	23 Sep 2020 16:40:22
	System	23 Sep 2020 16:40:22

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '22 Sep 2020 20:19'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 2'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:10', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144'	System	24 Sep 2020 14:46:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:13', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'None (0)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'None (0)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:19', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'None (0)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:22', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'None (0)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:24', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'None (0)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered 'No (N)'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-24T08:46:41', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'a8c7bd09-1350-4a4c-a68c-bfc40be18144' User entered '24 Sep 2020 08:46'	System	24 Sep 2020 14:46:42
	System	24 Sep 2020 14:46:42

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 3'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 4'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781'	System	25 Sep 2020 20:04:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:19', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'None (0)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:21', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'None (0)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'None (0)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:25', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'None (0)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:27', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'None (0)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:31', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered 'No (N)'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-25T14:04:33', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '637e4e79-0341-477e-b295-c8d162f93781' User entered '25 Sep 2020 14:04'	System	25 Sep 2020 20:04:40
	System	25 Sep 2020 20:04:40

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 5'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 6'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:45', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:47', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:49', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'None (0)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:56', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered 'No (N)'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-09-27T12:03:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e5f567d0-3693-43de-b665-b1c5c0e05abf' User entered '27 Sep 2020 12:03'	System	27 Sep 2020 18:04:01
	System	27 Sep 2020 18:04:01

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	22 Sep 2020 22:55:34
User entered 'Day 7'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 22:55:34

US3142252

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 22:55:34

US3142252

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4)	12 Nov 2020 18:44:42
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:29:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:29:18
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	28 Sep 2020 17:59:26
	(b) (4)	

US3142252

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:44:43
DataPoint Un-verified.		12 Nov 2020 18:29:32
DataPoint Verified.		12 Nov 2020 18:29:18
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		26 Oct 2020 12:09:13
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4)	19 Oct 2020 20:43:37
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 17:59:26
User entered '28 Sep 2020'	Dalia Jeronimo (b) (4)	28 Sep 2020 17:59:26

US3142252

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:44:45
DataPoint Un-verified.		12 Nov 2020 18:29:27
DataPoint Verified.		12 Nov 2020 18:29:18
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	28 Sep 2020 17:59:26
	(b) (4)	

US3142252

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:44:47
DataPoint Un-verified.		12 Nov 2020 18:29:28
DataPoint Verified.		12 Nov 2020 18:29:18
User entered empty.	Dalia Jeronimo (b) (4)	28 Sep 2020 17:59:26
	(b) (4)	

US3142252

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:30:07
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	28 Sep 2020 17:59:17

US3142252

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'I'	System	28 Sep 2020 17:59:17

US3142252

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:30:56
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:49:51

US3142252

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:30:56
User entered '6 Oct 2020'	Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:49:51

US3142252

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:30:56
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:49:51

US3142252

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:30:56
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:49:51

US3142252

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:31:07
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4) (b) (4)	08 Oct 2020 15:49:40

US3142252

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'I'	System	08 Oct 2020 15:49:40

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:48:35
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Oct 2020 21:28:50

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "site to add", kindly consider updating EDC as appropriate, if swab sample was collected on 13-Oct-2020 at illness visit, else clarify.' (Site from DM). User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	26 Apr 2021 16:08:31 26 Apr 2021 02:45:22
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "site to add", kindly consider updating EDC as appropriate, if swab sample was collected on 13-Oct-2020 at illness visit, else clarify.' answered with ' 12 OCT 2020 refers to contact made concerning COVID symptoms' (Site from DM). DataPoint Verified.	Jill York (b) (4) (b) (4), (b) (6)	19 Apr 2021 23:16:11 16 Dec 2020 17:32:56
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "site to add", kindly consider updating EDC as appropriate, if swab sample was collected on 13-Oct-2020 at illness visit, else clarify.' (Site from DM). User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:38:09 24 Nov 2020 05:38:09
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'site to add - duplicate query' (Site from DM).	Jill York (b) (4)	20 Nov 2020 20:27:48
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:22:35

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 21:51:08
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jami Wagner (b) (4)	12 Oct 2020 21:29:06
answered with 'Data entered is correct' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Oct 2020 21:28:50
User entered '12 Oct 2020'	Jami Wagner (b) (4)	12 Oct 2020 21:28:50
	(b) (4)	

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:48:38
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	12 Oct 2020 21:28:50

US3142252

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:48:40
User entered empty.	Jami Wagner (b) (4)	12 Oct 2020 21:28:50

US3142252

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:50:06
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Oct 2020 21:29:14

US3142252

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'I'	System	12 Oct 2020 21:29:14

US3142252

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4)	12 Nov 2020 18:51:55
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:51:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:50:38
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 20:59:41

US3142252

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:51:58
User entered '20 Oct 2020'	Jill York (b) (4)	21 Oct 2020 20:59:41

US3142252

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:52:00
User entered 'Clinic (Clinic)'	Jill York (b) (4)	21 Oct 2020 20:59:41

US3142252

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'VISIT3'	System	21 Oct 2020 20:59:41

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '20 Oct 2020'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '15:24'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '20 Oct 2020 15:24'	System	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '97.4' F	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered 'Other (Other)'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered 'temporal'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '74'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'bpm'	System	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '14'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'breaths/min'	System	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '138'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:55:48
User entered '97'	Jill York (b) (4)	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'mmHg'	System	21 Oct 2020 21:00:40

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37

US3142252

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37

US3142252

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:56:06
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 21:00:50

US3142252

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:56:06
User entered '20 Oct 2020'	Jill York (b) (4)	21 Oct 2020 21:00:50

US3142252

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:56:34
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 21:01:15

US3142252

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:56:34
User entered '20 Oct 2020'	Jill York (b) (4)	21 Oct 2020 21:01:15

US3142252

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:56:34
User entered '15:35'	Jill York (b) (4)	21 Oct 2020 21:01:15

US3142252

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered '20 Oct 2020 15:35'	System	21 Oct 2020 21:01:15

US3142252

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:56:40
User entered 'Yes (Y)'	Jill York (b) (4)	21 Oct 2020 21:01:20

US3142252

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'I'	System	21 Oct 2020 21:01:20

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 64'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-10-29T11:59:45', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f00f871-2ddb-480d-849f-e88aa6d02b91' User entered 'No (N)'	System	29 Oct 2020 17:59:59
	System	29 Oct 2020 17:59:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-10-29T11:59:50', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f00f871-2ddb-480d-849f-e88aa6d02b91'	System	29 Oct 2020 17:59:59
User entered 'No (N)'	System	29 Oct 2020 17:59:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-10-29T11:59:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '1f00f871-2ddb-480d-849f-e88aa6d02b91' User entered '29 Oct 2020 11:59:54'	System	29 Oct 2020 17:59:59
	System	29 Oct 2020 17:59:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 71'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-02T06:13:24', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '529e4a2a-e587-4cb0-a084-3b945e671e6c' User entered 'No (N)'	System	02 Nov 2020 13:13:37
	System	02 Nov 2020 13:13:37

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-02T06:13:28', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '529e4a2a-e587-4cb0-a084-3b945e671e6c' User entered 'No (N)'	System	02 Nov 2020 13:13:37
	System	02 Nov 2020 13:13:37

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-02T06:13:34', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '529e4a2a-e587-4cb0-a084-3b945e671e6c' User entered '02 Nov 2020 06:13:34'	System	02 Nov 2020 13:13:37
	System	02 Nov 2020 13:13:37

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:02:23
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59
Data entry locked.	System	25 Aug 2020 23:45:00
User entered 'Day 78'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 23:45:00

US3142252

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:50:59
Data entry locked.	System	25 Aug 2020 23:45:00
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 23:45:00

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-26T03:15:17', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b779c65a-e981-4610-854c-0b925fcede48' User entered 'No (N)'	System	26 Nov 2020 10:15:59
	System	26 Nov 2020 10:15:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-26T03:15:29', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b779c65a-e981-4610-854c-0b925fcede48'	System	26 Nov 2020 10:15:59
User entered 'Yes (Y)'	System	26 Nov 2020 10:15:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-26T03:15:38', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b779c65a-e981-4610-854c-0b925fcede48'	System	26 Nov 2020 10:15:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Nov 2020 10:15:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-11-26T03:15:48', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b779c65a-e981-4610-854c-0b925fcede48' User entered '26 Nov 2020 03:15:48'	System	26 Nov 2020 10:15:59
	System	26 Nov 2020 10:15:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-06T18:40:01', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8ccea463-769d-4bb8-bc3f-79ce6651ba92'	System	07 Dec 2020 01:40:16
User entered 'No (N)'	System	07 Dec 2020 01:40:16

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-06T18:40:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8ccea463-769d-4bb8-bc3f-79ce6651ba92'	System	07 Dec 2020 01:40:16
User entered 'No (N)'	System	07 Dec 2020 01:40:16

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-06T18:40:12', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8ccea463-769d-4bb8-bc3f-79ce6651ba92' User entered '06 Dec 2020 18:40:12'	System	07 Dec 2020 01:40:16
	System	07 Dec 2020 01:40:16

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-14T17:33:01', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8c2999d5-d643-4221-8953-05fadbc8b646' User entered 'No (N)'	System	15 Dec 2020 00:33:11
	System	15 Dec 2020 00:33:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-14T17:33:04', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8c2999d5-d643-4221-8953-05fadbc8b646'	System	15 Dec 2020 00:33:11
User entered 'No (N)'	System	15 Dec 2020 00:33:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-14T17:33:08', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8c2999d5-d643-4221-8953-05fadbc8b646' User entered '14 Dec 2020 17:33:08'	System	15 Dec 2020 00:33:11
	System	15 Dec 2020 00:33:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-19T12:01:51', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7d55568b-66c7-4293-9361-0999e7130fac'	System	19 Dec 2020 19:02:02
User entered 'No (N)'	System	19 Dec 2020 19:02:02

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-19T12:01:56', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7d55568b-66c7-4293-9361-0999e7130fac'	System	19 Dec 2020 19:02:02
User entered 'No (N)'	System	19 Dec 2020 19:02:02

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-19T12:02:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '7d55568b-66c7-4293-9361-0999e7130fac' User entered '19 Dec 2020 12:02:00'	System	19 Dec 2020 19:02:02
	System	19 Dec 2020 19:02:02

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-26T14:16:23', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '044837ac-f417-4f72-98e9-556dd8fb15c9' User entered 'No (N)'	System	26 Dec 2020 21:16:35
	System	26 Dec 2020 21:16:35

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-26T14:16:27', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '044837ac-f417-4f72-98e9-556dd8fb15c9' User entered 'No (N)'	System	26 Dec 2020 21:16:35
	System	26 Dec 2020 21:16:35

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-26T14:16:32', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '044837ac-f417-4f72-98e9-556dd8fb15c9' User entered '26 Dec 2020 14:16:32'	System	26 Dec 2020 21:16:35
	System	26 Dec 2020 21:16:35

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-31T02:12:39', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e83ca77d-0f89-4134-9a94-eb5269561fcd' User entered 'No (N)'	System	31 Dec 2020 09:12:55
	System	31 Dec 2020 09:12:55

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-31T02:12:45', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e83ca77d-0f89-4134-9a94-eb5269561fcd' User entered 'No (N)'	System	31 Dec 2020 09:12:55
	System	31 Dec 2020 09:12:55

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2020-12-31T02:12:52', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e83ca77d-0f89-4134-9a94-eb5269561fcd' User entered '31 Dec 2020 02:12:52'	System	31 Dec 2020 09:12:55
	System	31 Dec 2020 09:12:55

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-07T10:59:53', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8f2ab140-0bd7-4fe0-827a-0e99af88e751' User entered 'No (N)'	System	07 Jan 2021 18:00:37
	System	07 Jan 2021 18:00:37

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-07T10:59:55', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8f2ab140-0bd7-4fe0-827a-0e99af88e751'	System	07 Jan 2021 18:00:37
User entered 'No (N)'	System	07 Jan 2021 18:00:37

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-07T10:59:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '8f2ab140-0bd7-4fe0-827a-0e99af88e751' User entered '07 Jan 2021 10:59:58'	System	07 Jan 2021 18:00:37
	System	07 Jan 2021 18:00:37

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-15T17:40:49', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '559e9f91-9fb1-4023-a4d2-e6fcd429ec97'	System	15 Jan 2021 23:40:57
User entered 'No (N)'	System	15 Jan 2021 23:40:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-15T17:40:51', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '559e9f91-9fb1-4023-a4d2-e6fcd429ec97'	System	15 Jan 2021 23:40:57
User entered 'No (N)'	System	15 Jan 2021 23:40:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-15T17:40:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '559e9f91-9fb1-4023-a4d2-e6fcd429ec97' User entered '15 Jan 2021 17:40:54'	System	15 Jan 2021 23:40:57
	System	15 Jan 2021 23:40:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-28T07:16:51', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e0c5ea00-65fa-41e7-a847-ef9c0d125a70'	System	04 Feb 2021 12:49:57
User entered 'No (N)'	System	04 Feb 2021 12:49:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-28T07:16:54', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e0c5ea00-65fa-41e7-a847-ef9c0d125a70'	System	04 Feb 2021 12:49:57
User entered 'No (N)'	System	04 Feb 2021 12:49:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-01-28T07:16:58', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'e0c5ea00-65fa-41e7-a847-ef9c0d125a70' User entered '28 Jan 2021 07:16:58'	System	04 Feb 2021 12:49:57

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-04T05:49:57', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ea2c7a04-2293-47aa-a6ab-f451b3ae978c' User entered 'No (N)'	System	04 Feb 2021 12:50:11
	System	04 Feb 2021 12:50:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-04T05:50:03', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ea2c7a04-2293-47aa-a6ab-f451b3ae978c' User entered 'No (N)'	System	04 Feb 2021 12:50:11
	System	04 Feb 2021 12:50:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-04T05:50:07', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'ea2c7a04-2293-47aa-a6ab-f451b3ae978c' User entered '04 Feb 2021 05:50:07'	System	04 Feb 2021 12:50:11
	System	04 Feb 2021 12:50:11

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-11T19:46:40', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '861ce50c-626a-492c-bae1-bcfb9c0041ee' User entered 'No (N)'	System	12 Feb 2021 02:47:01
	System	12 Feb 2021 02:47:01

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-11T19:46:43', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '861ce50c-626a-492c-bae1-bcfb9c0041ee' User entered 'No (N)'	System	12 Feb 2021 02:47:01

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-11T19:46:47', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '861ce50c-626a-492c-bae1-bcfb9c0041ee' User entered '11 Feb 2021 19:46:47'	System	12 Feb 2021 02:47:01
	System	12 Feb 2021 02:47:01

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-20T15:56:02', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '387f3cf8-f70b-423c-be17-8d0f4246180c' User entered 'No (N)'	System	20 Feb 2021 22:56:12
	System	20 Feb 2021 22:56:12

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-20T15:56:05', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '387f3cf8-f70b-423c-be17-8d0f4246180c' User entered 'No (N)'	System	20 Feb 2021 22:56:12
	System	20 Feb 2021 22:56:12

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-20T15:56:09', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '387f3cf8-f70b-423c-be17-8d0f4246180c' User entered '20 Feb 2021 15:56:09'	System	20 Feb 2021 22:56:12
	System	20 Feb 2021 22:56:12

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:03-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6beb3d98-302a-4029-ba57-6326b501b712'	System	28 Feb 2021 19:01:13
User entered 'No (N)'	System	28 Feb 2021 19:01:13

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:04-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6beb3d98-302a-4029-ba57-6326b501b712'	System	28 Feb 2021 19:01:13
User entered 'No (N)'	System	28 Feb 2021 19:01:13

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:08-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '6beb3d98-302a-4029-ba57-6326b501b712'	System	28 Feb 2021 19:01:13
User entered '28 Feb 2021 19:01:08'	System	28 Feb 2021 19:01:13

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-04T05:50:04-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3ff02c88-3447-4502-b6d7-b157b68a4f28'	System	04 Mar 2021 12:50:18
User entered 'No (N)'	System	04 Mar 2021 12:50:18

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-04T05:50:07-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3ff02c88-3447-4502-b6d7-b157b68a4f28'	System	04 Mar 2021 12:50:18
User entered 'No (N)'	System	04 Mar 2021 12:50:18

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-04T05:50:12-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '3ff02c88-3447-4502-b6d7-b157b68a4f28' User entered '04 Mar 2021 05:50:12'	System	04 Mar 2021 12:50:18
	System	04 Mar 2021 12:50:18

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-11T05:39:06-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '50a607c8-14cb-4512-9ec2-a8e79ffe3e57'	System	11 Mar 2021 12:39:17
User entered 'No (N)'	System	11 Mar 2021 12:39:17

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-11T05:39:07-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '50a607c8-14cb-4512-9ec2-a8e79ffe3e57'	System	11 Mar 2021 12:39:17
User entered 'No (N)'	System	11 Mar 2021 12:39:17

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-11T05:39:12-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '50a607c8-14cb-4512-9ec2-a8e79ffe3e57'	System	11 Mar 2021 12:39:17
User entered '11 Mar 2021 05:39:12'	System	11 Mar 2021 12:39:17

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-18T08:15:36-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '17129b9e-d8ed-496a-b295-f98328a0c28d' User entered 'Yes (Y)'	System	18 Mar 2021 15:16:25
	System	18 Mar 2021 15:16:25

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-18T08:16:00-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '17129b9e-d8ed-496a-b295-f98328a0c28d' User entered 'No (N)'	System	18 Mar 2021 15:16:25
	System	18 Mar 2021 15:16:25

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-18T08:16:03-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '17129b9e-d8ed-496a-b295-f98328a0c28d' User entered 'No (N)'	System	18 Mar 2021 15:16:25
	System	18 Mar 2021 15:16:25

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-18T08:16:17-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '17129b9e-d8ed-496a-b295-f98328a0c28d' User entered 'No (N)'	System	18 Mar 2021 15:16:25
	System	18 Mar 2021 15:16:25

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-03-18T08:16:21-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: '17129b9e-d8ed-496a-b295-f98328a0c28d' User entered '18 Mar 2021 08:16:21'	System	18 Mar 2021 15:16:25
	System	18 Mar 2021 15:16:25

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:50:59

US3142252

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:50:59
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:50:59

US3142252

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:29-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b1b75c71-3959-4a47-a0d3-0e32cff14fa0'	System	28 Feb 2021 19:02:20
User entered 'Yes (Y)'	System	28 Feb 2021 19:02:20

US3142252

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:38-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b1b75c71-3959-4a47-a0d3-0e32cff14fa0'	System	28 Feb 2021 19:02:20
User entered 'No (N)'	System	28 Feb 2021 19:02:20

US3142252

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:03:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (575D8B5C-44CB-40E1-8E45-5CED07E6C274)', Time: '2021-02-28T12:01:44-07:00', User OID: 'PatientReportedOutcome (US3142252)', ODM File OID: 'b1b75c71-3959-4a47-a0d3-0e32cff14fa0' User entered '28 Feb 2021 19:01:44'	System	28 Feb 2021 19:02:20
	System	28 Feb 2021 19:02:20

US3142252

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
DataPoint Verified.		19 Apr 2021 23:07:57
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered 'Yes (Y)'	(b) (4)	
	Jami Wagner (b) (4)	16 Nov 2020 21:58:26
	(b) (4)	

US3142252

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
DataPoint Verified.		19 Apr 2021 23:07:57
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered '16 Nov 2020'	(b) (4) Jami Wagner (b) (4) (b) (4)	16 Nov 2020 21:58:26

US3142252

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
DataPoint Verified.		19 Apr 2021 23:07:57
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jami Wagner (b) (4) (b) (4)	16 Nov 2020 21:58:26

US3142252

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
DataPoint Verified.		19 Apr 2021 23:07:57
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered 'subject has already been in for a sick visit' reason for change: Data Entry Error	(b) (4)	
	Jami Wagner (b) (4)	16 Nov 2020 21:59:12
User entered empty.	(b) (4)	
	Jami Wagner (b) (4)	16 Nov 2020 21:58:26
	(b) (4)	

US3142252

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered 'Yes (Y)'	Jami Wagner (b) (4)	16 Nov 2020 21:58:32

US3142252

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:37
User entered 'I'	System	16 Nov 2020 21:58:32

US3142252

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
DataPoint Verified.		19 Apr 2021 23:08:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4)	
	Jami Wagner (b) (4)	23 Dec 2020 18:51:42
	(b) (4)	

US3142252

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
DataPoint Verified.		19 Apr 2021 23:08:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '17 Dec 2020'	(b) (4) Jami Wagner (b) (4) (b) (4)	23 Dec 2020 18:51:42

US3142252

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
DataPoint Verified.		19 Apr 2021 23:08:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jami Wagner (b) (4) (b) (4)	23 Dec 2020 18:51:42

US3142252

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
DataPoint Verified.		19 Apr 2021 23:08:22
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4)	
	Jami Wagner (b) (4)	23 Dec 2020 18:51:42
	(b) (4)	

US3142252

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	23 Dec 2020 18:51:47

US3142252

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:26
User entered 'I'	System	23 Dec 2020 18:51:47

US3142252

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	19 Jan 2021 00:26:57

US3142252

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '18 Jan 2021'	(b) (4)	
	Jami Wagner (b) (4)	19 Jan 2021 00:26:57
	(b) (4)	

US3142252

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	19 Jan 2021 00:26:57

US3142252

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	19 Jan 2021 00:26:57

US3142252

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4)	19 Jan 2021 00:27:03
	(b) (4)	

US3142252

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User entered 'I'	System	19 Jan 2021 00:27:03

US3142252

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	02 Apr 2021 17:02:10

US3142252

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:02:49
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data is as documented in clinical conductor' (Site from System).	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:13:34
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Apr 2021 17:02:10
User entered '15 Feb 2021'	Jami Wagner (b) (4) (b) (4)	02 Apr 2021 17:02:10

US3142252

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	02 Apr 2021 17:02:10

US3142252

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jami Wagner (b) (4)	02 Apr 2021 17:02:10
	(b) (4)	

US3142252

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 22:09:55

US3142252

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:06:47
User entered 'I'	System	11 Mar 2021 22:09:55

US3142252

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 22:10:12

US3142252

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '11 Mar 2021'	Jill York (b) (4)	11 Mar 2021 22:10:12

US3142252

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Clinic (Clinic)'	Jill York (b) (4)	11 Mar 2021 22:10:12

US3142252

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered 'VISIT4'	System	11 Mar 2021 22:10:12

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:29
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'No (N)'	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:32
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:34
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered empty.	System	05 Apr 2021 21:08:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:36
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:41
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:42
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:44
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered empty.	System	05 Apr 2021 21:08:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:46
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered empty.	System	05 Apr 2021 21:08:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:51
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered empty.	System	05 Apr 2021 21:08:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:48
DataPoint Verified.		21 Apr 2021 20:30:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	05 Apr 2021 21:08:25
	(b) (4)	

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered empty.	System	05 Apr 2021 21:08:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25

US3142252

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:21
DataPoint Verified.		21 Apr 2021 20:30:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'No (N)'	(b) (4) Jill York (b) (4)	11 Mar 2021 22:10:19

US3142252

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
DataPoint Un-verified.		21 Apr 2021 20:31:23
DataPoint Verified.		21 Apr 2021 20:30:44
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4) Jill York (b) (4)	11 Mar 2021 22:10:19

US3142252

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 22:10:35

US3142252

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '11 Mar 2021'	Jill York (b) (4)	11 Mar 2021 22:10:35

US3142252

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered '11:15'	Jill York (b) (4)	11 Mar 2021 22:10:35

US3142252

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered '11 Mar 2021 11:15'	System	11 Mar 2021 22:10:35

US3142252

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Yes (Y)'	Jill York (b) (4)	11 Mar 2021 22:10:41

US3142252

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:25
User entered 'I'	System	11 Mar 2021 22:10:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please enter con med from pt questionnaire and from Oct 13 and Nov 11 visit. ' (Site from CRA).	(b) (4)	24 Nov 2020 02:34:56
User closed query 'Please reconcile and enter the following missing pages: Illness Day 1 date, vitals, PE, blood draw, saliva log, and AE' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:39:58
Query 'Please enter con med from pt questionnaire and from Oct 13 and Nov 11 visit. ' answered with 'site to add conmeds with known data ' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:29:08
Query 'Please reconcile and enter the following missing pages: Illness Day 1 date, vitals, PE, blood draw, saliva log, and AE' answered with 'site can't complete saliva log yet because subject has not yet returned for day 29' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:22:57
User opened query 'Please reconcile and enter the following missing pages: Illness Day 1 date, vitals, PE, blood draw, saliva log, and AE' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:18:28
User opened query 'Please enter con med from pt questionnaire and from Oct 13 and Nov 11 visit. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:33:04
Query 'Please enter con med from pt questionnaire and from Nov 11 visit.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:32:16
User opened query 'Please enter con med from pt questionnaire and from Nov 11 visit.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:29:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:00:21
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:10:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:00:21
User entered '10:32'	Jill York (b) (4)	11 Nov 2020 23:10:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:26
User entered '11 Nov 2020 10:32'	System	11 Nov 2020 23:10:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:00:21
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jill York (b) (4)	11 Nov 2020 23:10:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:00:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:10:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 23:10:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:10:53
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:10:45
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:10:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 1 (Day 1)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
Query 'Per CDM; it appears that both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' are recorded as No on the Severity Form yet data is present. Please review and reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:13:17
User opened query 'Per CDM; it appears that both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' are recorded as No on the Severity Form yet data is present. Please review and reconcile.' (Site from DM).		08 Jan 2021 06:24:51
DataPoint Verified.		20 Nov 2020 22:40:43
User entered '07 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:36:42
User entered '7 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:53:56
User closed query ' Per CDM; Assessment Not Done is checked for Days 1-4 and 8 yet data is provided. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:17:28
Query ' Per CDM; Assessment Not Done is checked for Days 1-4 and 8 yet data is provided. Please review and reconcile' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 18:50:23
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	25 Jan 2021 18:49:08
User entered '0' reason for change: Data Entry Error	Meghan York (b) (4)	25 Jan 2021 18:49:08
User opened query ' Per CDM; Assessment Not Done is checked for Days 1-4 and 8 yet data is provided. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 06:13:09
DataPoint Verified.		20 Nov 2020 22:40:43
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:23:16
User entered '0'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:53:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	25 Jan 2021 18:49:08
DataPoint Un-verified.	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:47:11
User entered empty; reason for change Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:47:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:23:16
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	25 Jan 2021 18:49:08
User entered empty.	System	25 Jan 2021 18:47:11
User entered '%'	System	20 Nov 2020 16:23:16
User entered empty.	System	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:53:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	25 Jan 2021 18:49:08
DataPoint Un-verified.	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:47:11
User entered empty; reason for change Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:47:11
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:23:16
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:33:57

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 2 (Day 2)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:09:31
User entered '08 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:54:05
DataPoint Un-verified.	Meghan York (b) (4)	25 Jan 2021 18:49:17
User entered '0' reason for change: Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:49:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
DataPoint Un-verified.	Jill York (b) (4)	20 Nov 2020 19:14:28
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:14:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:09:32
User entered '0'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 03:47:23
User closed query 'Please enter Sat from SD' (Site from CRA).		20 Nov 2020 03:47:19
Query 'Please enter Sat from SD' answered with 'done' (Site from CRA).	Jill York (b) (4)	13 Nov 2020 20:20:23
DataPoint Un-verified.	Jill York (b) (4)	13 Nov 2020 20:19:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	13 Nov 2020 20:19:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:13:15
User opened query 'Please enter Sat from SD' (Site from CRA).		12 Nov 2020 19:13:08
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	13 Nov 2020 20:19:45
User entered empty.	System	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 03:47:22
User closed query 'Please enter temp from SD' (Site from CRA).		20 Nov 2020 03:47:21
Query 'Please enter temp from SD' answered with 'done' (Site from CRA).	Jill York (b) (4)	13 Nov 2020 20:20:25
DataPoint Un-verified.	Jill York (b) (4)	13 Nov 2020 20:19:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	13 Nov 2020 20:19:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:13:17
User opened query 'Please enter temp from SD' (Site from CRA).		12 Nov 2020 19:13:10
DataPoint Un-verified.		12 Nov 2020 19:11:45
DataPoint Verified.		12 Nov 2020 19:11:42
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:14:10
DataPoint Un-verified.		12 Nov 2020 19:14:03
DataPoint Verified.		12 Nov 2020 19:13:33
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:13:35
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:14:18
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:15:01
DataPoint Un-verified.		12 Nov 2020 19:14:37
DataPoint Verified.		12 Nov 2020 19:14:28
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:15:10
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:15:17
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:15:27
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:15:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User closed query 'Please reconcile w source' (Site from CRA).		20 Nov 2020 03:47:40
Query 'Please reconcile w source' answered with 'done' (Site from CRA).	Jill York (b) (4)	13 Nov 2020 20:20:34
DataPoint Un-verified.	Jill York (b) (4)	13 Nov 2020 20:19:45
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	13 Nov 2020 20:19:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:17:48
User opened query 'Please reconcile w source' (Site from CRA).		12 Nov 2020 19:17:44
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	13 Nov 2020 20:19:45
Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:17:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:17:50
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:18:51
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:19:25
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:19:32
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:20:32
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:20:13
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:20:39
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:36:21

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 3 (Day 3)'	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:39:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 23:39:47
User entered '09 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:36:42
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:54:18
DataPoint Un-verified.	Meghan York (b) (4)	25 Jan 2021 18:49:24
User entered '0' reason for change: Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:26:53
User entered '0'	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:26:53
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 16:26:53
User entered empty.	System	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:26:53
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	11 Nov 2020 23:39:47
Data Entry Error		
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	11 Nov 2020 23:39:47
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:36:42

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 4 (Day 4)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '10 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:54:27
DataPoint Un-verified.	Meghan York (b) (4)	25 Jan 2021 18:50:09
User entered '0' reason for change: Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:50:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:30:15
User entered '0'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:30:15
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 16:30:15
User entered empty.	System	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:30:15
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:48:05

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add all missing days from 12Nov2020 through 16Nov2020' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:47:51
Query 'Please reconcile and add all missing days from 12Nov2020 through 16Nov2020' answered with 'ok' (Site from CRA).	Jill York (b) (4)	19 Nov 2020 23:47:12
User opened query 'Please reconcile and add all missing days from 12Nov2020 through 16Nov2020' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:19:22
User entered 'Day 5 (Day 5)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '90' reason for change: Data Entry Error	Jill York (b) (4)	13 Nov 2020 20:18:39
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	13 Nov 2020 20:18:39
User entered empty.	System	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.1' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:38:52
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)'	Jill York (b) (4)	11 Nov 2020 23:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 6 (Day 6)'	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 01:14:22
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'ok' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 16:39:13
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:11
User entered '12 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '94' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 16:45:13
User entered empty.	System	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.7' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	20 Nov 2020 16:45:13
Data Entry Error		
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	20 Nov 2020 16:45:13
Data Entry Error		
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	20 Nov 2020 16:45:13
Data Entry Error		
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:45:13
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:49:52

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 7 (Day 7)'	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 01:14:37
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'ok' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 16:45:36
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:21
User entered '13 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:50:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '93' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 16:47:38
User entered empty.	System	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.9' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	20 Nov 2020 16:47:38
Data Entry Error		
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 16:47:38
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:10

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 8 (Day 8)'	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:51:25
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 19:54:16
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:28
User entered '14 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:58:32
DataPoint Un-verified.	Meghan York (b) (4)	25 Jan 2021 18:50:09
User entered '0' reason for change: Data Entry Error	(b) (4) Meghan York (b) (4)	25 Jan 2021 18:50:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '96' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 19:56:58
User entered empty.	System	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '98.0' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	20 Nov 2020 19:56:58
Data Entry Error		
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:56:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:25

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 9 (Day 9)'	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:25:11
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 19:57:21
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:34
User entered '15 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '95' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 19:59:06
User entered empty.	System	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.8' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 19:59:06
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:50:45

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 10 (Day 10)'	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:52:29
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 19:59:22
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:43
User entered '16 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:51:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '94' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 20:00:58
User entered empty.	System	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '98.0' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:00:58
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:51:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 11 (Day 11)'	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4)	20 Nov 2020 22:53:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:11:16
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:49
User entered '17 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 20:13:47
User entered empty.	System	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '98.0' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:13:47
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:00

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 12 (Day 12)'	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4)	20 Nov 2020 22:53:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:14:47
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:46:58
User entered '18 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:53:18

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '93' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 20:16:25
User entered empty.	System	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.7' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:29:31
DataPoint Un-verified.	Jill York (b) (4)	23 Nov 2020 21:59:37
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	23 Nov 2020 21:59:37
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:55:59
DataPoint Un-verified.		20 Nov 2020 22:59:26
DataPoint Verified.		20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:16:25
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:18

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 13 (Day 13)'	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:59:45
DataPoint Verified.		20 Nov 2020 22:40:43
Query 'Please reconcile and add symptoms as they were required to be collected daily from subject' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:16:49
User opened query 'Please reconcile and add symptoms as they were required to be collected daily from subject' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 03:47:04
User entered '19 Nov 2020'	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '0'	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '93' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	20 Nov 2020 20:19:19
User entered empty.	System	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered '97.7' F reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:29:48
DataPoint Un-verified.	Jill York (b) (4)	23 Nov 2020 21:59:37
User entered 'Severe (Severe)' reason for change:	Jill York (b) (4)	23 Nov 2020 21:59:37
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:55:47
DataPoint Un-verified.		20 Nov 2020 23:03:10
DataPoint Verified.		20 Nov 2020 22:40:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:40:43
User entered 'None (None)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:19:19
User entered empty.	Jill York (b) (4)	19 Nov 2020 23:53:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 14 (Day 14)'	Jill York (b) (4)	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '20 Nov 2020'	Jill York (b) (4)	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '0'	Jill York (b) (4)	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '96'	Jill York (b) (4)	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '98.0' F	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Severe (Severe)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:48:28

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 15 (Day 15)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '21 Nov 2020'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '0'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '95'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '97.7' F	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Severe (Severe)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:50:36

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 16 (Day 16)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '22 Nov 2020'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '0'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '95'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	23 Nov 2020 21:52:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '97.0' F	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Severe (Severe)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:52:15

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Day 17 (Day 17)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User closed query 'Please enter contact attempts and assessments for 24Nov-01Dec.' (Site from CRA).		21 Apr 2021 18:13:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
Query 'Please enter contact attempts and assessments for 24Nov-01Dec.' answered with 'is this the same as the symptom log? Should the site be adding this form or if not, please direct site as to where to find the telemedicine EDC forms to complete. Thanks.' (Site from CRA).	Jill York (b) (4)	08 Apr 2021 22:11:06
User opened query 'Please enter contact attempts and assessments for 24Nov-01Dec.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:08:16
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '23 Nov 2020'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '0'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '96'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User entered '%'	System	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered '97.7' F	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jill York (b) (4)	23 Nov 2020 22:00:34
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'Severe (Severe)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:20:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 00:17:46
User entered 'None (None)'	Jill York (b) (4)	23 Nov 2020 21:53:41

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4)	22 Nov 2020 01:56:17
Query 'Please verify as there are no central results yet' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:17:48
User opened query 'Please verify as there are no central results yet' (Site from CRA).		16 Nov 2020 01:03:41
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered 'Yes (Y)'	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
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). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 11:38:37
		22 Nov 2020 01:56:17
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 'Will provide' (Site from System).	Jill York (b) (4)	11 Nov 2020 23:17:12
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	11 Nov 2020 23:15:20
User entered 'Yes (Y)'	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:15:20

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 01:56:17
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:20:38

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:45
User entered 'I'	System	11 Nov 2020 23:15:20

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

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 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

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 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'Yes (Y)'	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per CDM, Per Sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify	(b) (4) (b) (4), (b) (6)	22 Apr 2021 08:16:16
' (Site from DM). DataPoint Verified.		21 Apr 2021 20:29:21
Query 'Per CDM, Per Sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify	Jill York (b) (4)	21 Apr 2021 17:45:39
' answered with 'done ' (Site from DM). DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 17:44:42
User entered '11 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 17:44:42
User opened query 'Per CDM, Per Sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify	(b) (4), (b) (6)	09 Apr 2021 08:49:01
' (Site from DM). DataPoint Verified.		24 Nov 2020 02:35:18
User closed query 'Please remove end date as still ongoing <= 93% at last symptom log entry' (Site from CRA).		24 Nov 2020 02:35:14
Query 'Please remove end date as still ongoing <= 93% at last symptom log entry' answered with 'updated' (Site from CRA).	Jill York (b) (4)	23 Nov 2020 21:44:43
DataPoint Un-verified.	Jill York (b) (4)	23 Nov 2020 21:44:30
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	23 Nov 2020 21:44:30

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Audit	User	Time (GMT)
User opened query 'Please remove end date as still ongoing <= 93% at last symptom log entry' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 01:15:23
		20 Nov 2020 23:13:11
User entered '11 Nov 2020'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User closed query 'Please reconcile as symptom log notes value of 90% but blank on severity page' (Site from CRA).		20 Nov 2020 23:12:48
Query 'Please reconcile as symptom log notes value of 90% but blank on severity page' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:28:36
User entered '90' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:28:10
User opened query 'Please reconcile as symptom log notes value of 90% but blank on severity page' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:19:54
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per CDM: It appears that both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' are recorded as No on the Severity Form yet data is present. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 06:32:51
Query 'Per CDM: It appears that both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' are recorded as No on the Severity Form yet data is present. Please review and reconcile.' answered with 'corrected ' (Site from DM).	Jill York (b) (4)	01 Mar 2021 19:36:57
User opened query 'Per CDM: It appears that both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' are recorded as No on the Severity Form yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:14:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:21
DataPoint Un-verified.	Jill York (b) (4)	01 Mar 2021 19:36:42
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:36:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:21
DataPoint Un-verified.	Jill York (b) (4)	01 Mar 2021 19:36:42
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:36:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:21
DataPoint Un-verified.	Jill York (b) (4)	01 Mar 2021 19:36:42
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:36:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

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[ECMO?](#)

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DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:21
DataPoint Un-verified.	Jill York (b) (4)	01 Mar 2021 19:36:42
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:36:42
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
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[Evidence of Shock Requires
Vasopressors](#)

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User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
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[Hepatic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:13:11
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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:20:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:13:11
User entered empty.	Jill York (b) (4)	11 Nov 2020 23:21:33

US3142252

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:20:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:07:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:12:01
User entered 'No (N)'	Jill York (b) (4)	11 Nov 2020 23:15:40

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva : Requery: response is ambiguous, please elaborate.Thanks' (Site from DM).	(b) (4), (b) (6)	02 May 2021 09:20:59
Query 'Per GCL Lab Reconciliation: Saliva : Requery: response is ambiguous, please elaborate.Thanks' answered with 'site is repeating the same response. Site does not have a lab requisition indicating that the subject returned the saliva samples. Please clarify what site should do if we don't have any records of the saliva samples being sent to the lab.' (Site from DM).	Jill York (b) (4)	01 May 2021 17:35:08
User opened query 'Per GCL Lab Reconciliation: Saliva : Requery: response is ambiguous, please elaborate.Thanks' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 08:12:01
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 17DEC2020(Accession # 1F657459244) is reported. Hence please confirm correct date of collection and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results. (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 08:12:01
Query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 17DEC2020(Accession # 1F657459244) is reported. Hence please confirm correct date of collection and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results. ' answered with 'site does not have source or lab requisition indicating that the subject returned saliva samples?' (Site from DM).	Jill York (b) (4)	23 Apr 2021 15:58:03

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is No, however in PPD Central Lab sample dated 17DEC2020(Accession # 1F657459244) is reported. Hence please confirm correct date of collection and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 09:45:34
User accepted default value 'Day 28 (Day 28)'	Lisa Jackson (b) (4) (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 21:31:31

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4)	
	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
	(b) (4)	
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered empty.	(b) (4)	
	Jill York (b) (4)	19 Apr 2021 23:13:37

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User closed query 'Per ETRTR, Saliva collection page is empty. According to PPD Labs no saliva samples have been collected/received. Please confirm and complete EDC accordingly. If Saliva samples were not collected please ensure a PD is recorded.' (Site from CRA).		29 Apr 2021 23:56:11
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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) (4), (b) (6)	23 Apr 2021 20:42:25
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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 'added' (Site from DM).	Jill York (b) (4)	19 Apr 2021 23:05:09
Query 'Per ETRTR, Saliva collection page is empty. According to PPD Labs no saliva samples have been collected/received. Please confirm and complete EDC accordingly. If Saliva samples were not collected please ensure a PD is recorded.' answered with 'saliva log has been added' (Site from CRA).	Jill York (b) (4)	19 Apr 2021 23:04:16
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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 Dec 2020 09:01:58

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per source, Illness visit 1 was conducted on 13Oct2020. Please verify and correct.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 17:37:34
User opened query 'Per source, Illness visit 1 was conducted on 13Oct2020. Please verify and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 17:35:08
User opened query 'Per ETRTR, Saliva collection page is empty. According to PPD Labs no saliva samples have been collected/received. Please confirm and complete EDC accordingly. If Saliva samples were not collected please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 18:05:23
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:29:09
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however Covid-19 Assessment and Covid-19 Diagnostic form in EDC not updated. Please reconcile the data and update. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 13:21:05
	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however Covid-19 Assessment and Covid-19 Diagnostic form in EDC not updated. Please reconcile the data and update. Thank you.' answered with '? COVID diagnostic test form is present' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however Covid-19 Assessment and Covid-19 Diagnostic form in EDC not updated. Please reconcile the data and update. Thank you.' (Site from DM). User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 13OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	Jill York (b) (4)	21 Apr 2021 23:27:57
	(b) (4), (b) (6)	21 Apr 2021 12:11:12
	(b) (4), (b) (6)	21 Apr 2021 12:11:12
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 13OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'illness visit added' (Site from DM). DataPoint Verified.	Jill York (b) (4)	19 Apr 2021 23:10:00
	(b) (4), (b) (6)	16 Dec 2020 17:37:38
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 17:35:32

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 13OCT2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 12:20:58
		20 Nov 2020 22:29:12
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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) (4), (b) (6)	23 Apr 2021 09:41:39
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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 'per source, subject did not return saliva samples' (Site from DM).	Jill York (b) (4)	19 Apr 2021 23:09:33
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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)	24 Dec 2020 07:48:27
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:29:12
User entered 'Clinic (Clinic)'	Jill York (b) (4)	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'SICKD1'	System	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:32
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:03:57
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:35
User entered '14:20'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered '11 Nov 2020 14:20'	System	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:37
User entered missing code ND - Not Done.	Jill York (b) (4)	20 Nov 2020 20:25:40
DataPoint set to visible.	System	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:03:53
User entered missing code ND - Not Done.	Jill York (b) (4)	20 Nov 2020 20:25:40
DataPoint set to visible.	System	20 Nov 2020 20:24:14

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:39
User entered '97.1' F	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:41
User entered 'Other (Other)'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:43
User entered 'temporal'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:48
User entered '80'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'bpm'	System	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:50
User entered '15'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'breaths/min'	System	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:52
User entered '140'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'mmHg'	System	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:29:58
User entered '89'	Jill York (b) (4)	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'mmHg'	System	20 Nov 2020 20:25:40

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:32:02
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 20:25:50

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:32:04
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:25:50

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[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 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Please enter Convalescence visit Day 28 according to source.' (Site from CRA).	(b) (4)	21 Apr 2021 21:14:13
Query 'Please enter Convalescence visit Day 28 according to source.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	21 Apr 2021 17:47:28
User opened query 'Please enter Convalescence visit Day 28 according to source.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:15:54
DataPoint Verified.		20 Nov 2020 22:32:14
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 20:26:02

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:32:16
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:26:02

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:23:51
User entered 'Yes (Y)'	Jill York (b) (4)	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:23:51
User entered '13 Oct 2020'	Jill York (b) (4)	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:23:51
User entered 'Clinic (Clinic)'	Jill York (b) (4)	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'SICKD1'	System	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered 'Yes (Y)'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '13 Oct 2020'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '16:50'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered '13 Oct 2020 16:50'	System	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered missing code ND - Not Done.	Jill York (b) (4)	19 Apr 2021 23:12:31
DataPoint set to visible.	System	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered missing code ND - Not Done.	Jill York (b) (4)	19 Apr 2021 23:12:31
DataPoint set to visible.	System	19 Apr 2021 23:11:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '97.3' F	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered 'Other (Other)'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered 'temporal'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '57'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'bpm'	System	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '17'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'breaths/min'	System	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '120'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'mmHg'	System	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:05
User entered '80'	Jill York (b) (4)	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User entered 'mmHg'	System	19 Apr 2021 23:12:31

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39

US3142252

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:19
User entered 'Yes (Y)'	Jill York (b) (4)	19 Apr 2021 23:12:41

US3142252

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:19
User entered '13 Oct 2020'	Jill York (b) (4)	19 Apr 2021 23:12:41

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[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 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:37
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	19 Apr 2021 23:12:55

US3142252

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:39
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:37
User entered '13 Oct 2020'	Jill York (b) (4)	19 Apr 2021 23:12:55

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:00
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	19 Apr 2021 14:35:53

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:00
User entered '17 Dec 2020'	Lisa Jackson (b) (4)	19 Apr 2021 14:35:53

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:00
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:35:53

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'SICKD28'	System	19 Apr 2021 14:35:53

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '17 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '11:19'	Lisa Jackson (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered '17 Dec 2020 11:19'	System	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '97.7' F	Lisa Jackson (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered 'Other (Other)'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered 'TEMPORAL'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '77'	Lisa Jackson (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'bpm'	System	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '16'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'breaths/min'	System	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '140'	Lisa Jackson (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'mmHg'	System	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:10
User entered '86'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'mmHg'	System	19 Apr 2021 14:37:14

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:23
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	19 Apr 2021 14:37:35

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:04:23
User entered '17 Dec 2020'	Lisa Jackson (b) (4)	19 Apr 2021 14:37:35

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[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 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:33
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:58

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:04:33
User entered '17 Dec 2020'	Lisa Jackson (b) (4) (b) (4)	19 Apr 2021 14:37:58

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:25:57
User entered 'No (N)'	Jill York (b) (4)	19 Apr 2021 23:13:05

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:25:57
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:05

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:25:57
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:05

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered 'SICKD28'	System	19 Apr 2021 23:13:05

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered 'No (N)'	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered empty.	System	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered empty.	System	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered empty.	System	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered empty.	System	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:13
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User entered empty.	System	19 Apr 2021 23:13:12

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:23
User entered 'No (N)'	Jill York (b) (4)	19 Apr 2021 23:14:00

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:23
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:14:00

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[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 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:33
User entered 'NA (COVID-19 Negative) (NA)'	Jill York (b) (4)	19 Apr 2021 23:13:19

US3142252

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:20:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:23
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:33
User entered empty.	Jill York (b) (4)	19 Apr 2021 23:13:19

US3142252

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:06:47

US3142252

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:06:47

US3142252

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:06:47

US3142252

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'UNBLND_DECIDE'	System	23 Mar 2021 19:06:47

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
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 20:27:34
Query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'Data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:26:53
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:26:42
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 16:40:16
User entered 'mRNA-1273 (mRNA-1273)'		23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'I'	System	23 Mar 2021 19:07:46

US3142252

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'I'	System	23 Mar 2021 19:07:46

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered empty.	System	23 Mar 2021 19:09:11
DataPoint set to visible.	System	23 Mar 2021 19:07:46

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered empty.	System	23 Mar 2021 19:09:11
DataPoint set to visible.	System	23 Mar 2021 19:07:46

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User accepted default value 'Pre-Dose (PREDOSE)'		23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11:03'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered '11 Mar 2021 11:03'	System	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '96'	(b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'bpm'	System	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '10'	(b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'breaths/min'	System	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '134'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'mmHg'	System	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '97'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'mmHg'	System	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:09:11

US3142252

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered empty.	System	23 Mar 2021 19:09:11
DataPoint set to visible.	System	23 Mar 2021 19:07:46

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User accepted default value 'Post-Dose (POSTDOSE)'		23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11:54'	(b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered '11 Mar 2021 11:54'	System	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '65'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'bpm'	System	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '10'	(b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'breaths/min'	System	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '137'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'mmHg'	System	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '88'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:15

US3142252

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'mmHg'	System	23 Mar 2021 19:10:15

US3142252

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:43

US3142252

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:10:43

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'mRNA-1273'	System	23 Mar 2021 19:12:07
DataPoint set to visible.	System	23 Mar 2021 19:07:46

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11:24'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered '11 Mar 2021 11:24'	System	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'ONCE'	System	23 Mar 2021 19:12:07

US3142252

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

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'INTRAMUSCULAR'	System	23 Mar 2021 19:12:07

US3142252

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 19:12:29

US3142252

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:12:29

US3142252

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11:03'	(b) (4), (b) (6)	23 Mar 2021 19:12:29

US3142252

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered '11 Mar 2021 11:03'	System	23 Mar 2021 19:12:29

US3142252

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:33

US3142252

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:33

US3142252

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11:16'	(b) (4), (b) (6)	23 Mar 2021 19:17:33

US3142252

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered '11 Mar 2021 11:16'	System	23 Mar 2021 19:17:33

US3142252

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

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:37

US3142252

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

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:26
User entered 'I'	System	23 Mar 2021 19:17:37

US3142252

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:52

US3142252

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:11:57
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 'information is correct as entered' (Site from System).		23 Mar 2021 19:19:30
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 Mar 2021 19:17:52
User entered '23 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:17:52

US3142252

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:52

US3142252

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:17:52

US3142252

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:32:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:19:43

US3142252

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User entered 'I'	System	23 Mar 2021 19:19:43

US3142252

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:13
User entered '1'	System	23 Mar 2021 19:19:43
DataPoint set to visible.	System	23 Mar 2021 19:19:43

US3142252

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered 'Yes (Y)'	Jill York (b) (4)	14 Apr 2021 18:17:06

US3142252

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered '14 Apr 2021'	Jill York (b) (4)	14 Apr 2021 18:17:06

US3142252

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 21:39:30
User entered 'Clinic (Clinic)'	Jill York (b) (4)	14 Apr 2021 18:17:06

US3142252

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	14 Apr 2021 18:17:06

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered empty.	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered empty.	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered empty.	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered empty.	Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:17:38

US3142252

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:17:48

US3142252

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered '14 Apr 2021'	Jill York (b) (4)	14 Apr 2021 18:17:48

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered 'No (N)'	Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Other (OTHER)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'subject declined due to solicited adverse events (not AEs due to not lasting longer than 7 days post dose)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:19:25
DataPoint set to visible.	System	23 Mar 2021 19:19:43

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered empty.	Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:19:25

US3142252

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	14 Apr 2021 18:19:32

US3142252

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 18:19:32

US3142252

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:20:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:32:40
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 21:00:23

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4)	16 Dec 2020 15:22:50
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:47:06
User entered	System	25 Nov 2020 13:46:56
'USA-US064-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	25 Nov 2020 13:46:56

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:48
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)	20 Nov 2020 21:07:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:07:03
Data point term sent to Coder	System	20 Nov 2020 21:05:56
User entered 'COVID-19 infection'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:51
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:53
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:55
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:57
User entered '7 Nov 2020'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:16:58
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	14 Apr 2021 19:50:51
DataPoint Un-verified.	System	14 Apr 2021 19:50:51
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	14 Apr 2021 19:50:51
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Jill York (b) (4)	14 Apr 2021 19:50:51
DataPoint Verified.	System	14 Apr 2021 19:49:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Nov 2020 20:17:04
	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
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)	15 Apr 2021 19:18:11
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 date' (Site from Safety).	Jill York (b) (4)	14 Apr 2021 19:50:23
DataPoint Un-verified.	Jill York (b) (4)	14 Apr 2021 19:49:29
User entered '01 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	14 Apr 2021 19:49:29
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)	07 Dec 2020 20:57:23
DataPoint Verified.		22 Nov 2020 20:17:01
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:10
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:13
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		20 Nov 2020 21:09:34
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	20 Nov 2020 21:05:31
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 21:09:34
User entered '1'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered 'Not Applicable (NOT APPLICABLE)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

None

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered 'I'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered '0'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
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)	15 Apr 2021 19:15:42
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 'added end date' (Site from Safety).	Jill York (b) (4)	14 Apr 2021 19:50:36
DataPoint Un-verified.	Jill York (b) (4)	14 Apr 2021 19:49:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jill York (b) (4)	14 Apr 2021 19:49:29
Data Entry Error	(b) (4), (b) (6)	
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).		07 Dec 2020 20:57:37
DataPoint Verified.		22 Nov 2020 20:17:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[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 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered empty.	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 20:17:24
User entered 'Subject became symptomatic for COVID-19 07NOV2020. Subject obtained COVID-19 testing 09NOV2020 (not at site). Subject contacted site 11NOV2020 to inform site that her COVID-19 test came back positive. Subject came to site in the afternoon of 11NOV2020 for an illness visit. All study procedures completed for illness visit. Subject's study COVID-19 test came back positive. Subject remains symptomatic at the time of this data entry.'	Jill York (b) (4)	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 21:05:31

US3142252

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:05:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:49
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 06:43:33
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'added botox to source and conmeds' (Site from DM).	Jill York (b) (4)	22 Apr 2021 21:18:57
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 03:06:18
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject reports that no medication was taken at this time ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 17:43:46

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 09:11:19
		13 Jan 2021 11:23:14
		18 Nov 2020 20:27:20
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 16:39:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
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: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 18:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	25 Jan 2021 18:47:55
Data point term sent to Coder Coding entries removed.	System Meghan York (b) (4)	25 Jan 2021 18:47:06 25 Jan 2021 18:46:08
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: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 16:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	13 Nov 2020 16:42:46
Data point term sent to Coder User entered 'Advil'	System Meghan York (b) (4)	13 Nov 2020 16:41:38 13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query ' Per DM CLR: Please note that there is no AE matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 10:13:53
Query ' Per DM CLR: Please note that there is no AE Jill York matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' answered with 'not considered an AE' (Site from DM).	(b) (4)	07 Apr 2021 19:09:25

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 03:30:19
User closed query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' (Site from DM).		29 Jan 2021 04:24:28
Query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' answered with 'location and type of pain unknown' (Site from DM).	Meghan York (b) (4)	25 Jan 2021 18:46:13
User entered 'PAIN AFTER SECOND VACCINATION (location and type of pain unknown)' reason for change: Data Entry Error	Meghan York (b) (4)	25 Jan 2021 18:46:08
User opened query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:56:10
User entered 'pain after second vaccination'	Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '400'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'mg (mg)'	(b) (4) Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'once daily (QD)'	(b) (4) Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Oral (ORAL)'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '24 Sep 2020'	(b) (4) Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '25 Sep 2020'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User entered '1'	System	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User entered '1'	System	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:31
User entered '804 (804)'	System	13 Nov 2020 16:40:48

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Nov 2020 20:33:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:33:02
Data point term sent to Coder	System	20 Nov 2020 20:31:53
User entered 'synthroid'	Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'hypothyroidism'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose and dose unit for this medication. Please correct the dosage and unit or provide explanation for alternate dosage and unit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 12:39:27
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose and dose unit for this medication. Please correct the dosage and unit or provide explanation for alternate dosage and unit.' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Feb 2021 18:15:59
User entered '12.5' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	01 Feb 2021 18:15:48
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose and dose unit for this medication. Please correct the dosage and unit or provide explanation for alternate dosage and unit.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:04:35
User entered '0.5'	Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Meghan York (b) (4)	01 Feb 2021 18:15:48
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered 'mcg' reason for change: Data Entry Error	Meghan York (b) (4)	01 Feb 2021 18:15:48
	(b) (4)	
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'once daily (QD)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Oral (ORAL)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'un UNK 1984'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:31:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 20:31:08
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	20 Nov 2020 20:31:08
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 20:30:53
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 20:30:53

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:14
Data point term sent to Coder	System	20 Nov 2020 20:37:00
User entered 'Zithromax'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'COVID-19'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '500'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'mg (mg)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'once (ONCE)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Oral (ORAL)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User entered empty.	System	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User entered empty.	System	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:20
User entered empty.	System	20 Nov 2020 20:36:16

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:14
Data point term sent to Coder	System	20 Nov 2020 20:38:02
User entered 'zithromax'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'COVID-19'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '250'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'mg (mg)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'once daily (QD)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Oral (ORAL)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '12 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '14 Nov 2020'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User entered '1'	System	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User entered '1'	System	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:09:24
User entered '804 (804)'	System	20 Nov 2020 20:37:50

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
Query 'Please add the Zinc, Vit C and Vit D and doses as unknown.' canceled (Site from CRA).	(b) (4)	
User opened query 'Please add the Zinc, Vit C and Vit D and doses as unknown.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:36:57
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: HYDROXYCHLOROQUINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:41:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 20:41:02
Data point term sent to Coder	System	20 Nov 2020 20:40:05
User entered 'hydroxychloroquine'	Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'COVID-19'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '200'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'mg (mg)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'twice daily (BID)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Oral (ORAL)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '11 Nov 2020'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '0'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered empty.	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'No (N)'	(b) (4) Jill York (b) (4)	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 20:39:11

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 01:51:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 01:51:38
Data point term sent to Coder User entered 'Botox'	System Lisa Jackson (b) (4)	22 Apr 2021 21:07:23 22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Prevention of wrinkles in the forehead and between the eyebrows'	(b) (4) Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered '20-30'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Other (OTHER)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'units' reason for change: Data Entry Error	(b) (4)	
	Jill York (b) (4)	22 Apr 2021 21:17:56
User entered 'Subject did not know exactly the measurement but stated several times'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31
	(b) (4)	

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'other (OTHER)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Subject stated several times a year'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Other (OTHER)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'Injected into the forehead and between the eyebrows'	(b) (4) Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'un UNK 2019'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered '0'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'No (N)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'un UNK 2020'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:22
User entered 'No (N)'	Lisa Jackson (b) (4)	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User entered empty.	System	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User entered empty.	System	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:13:21
User entered empty.	System	22 Apr 2021 21:06:31

US3142252

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:20:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 21:15:20
	(b) (4)	

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'USA-US064-2020-MRNA-1273-P301000006'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Ripley'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Hollister'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '4190 East Woodmen Road Suite 210'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Colorado Springs'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '80920'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
User entered 'US'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 19:37:11
User entered '1'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'USA-US064-2020-MRNA-1273-P301000006'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Ripley'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Hollister'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '4190 East Woodmen Road Suite 210'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Colorado Springs'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '80920'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
User entered 'US'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 19:37:11
User entered '1'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:20:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
User entered '25/Nov/2020 08:47'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:20:38

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 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
User entered 'I'		25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'USA-US064-2020-MRNA-1273-P301000006'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'No (N)'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Ripley'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Hollister'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '4190 East Woodmen Road Suite 210'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered 'Colorado Springs'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
Reviewed for Safety.		25 Nov 2020 13:47:18
User entered '80920'	System	25 Nov 2020 13:46:56

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:22:42
User entered 'US'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 19:37:11
User entered '1'	System	25 Nov 2020 13:47:23

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:20:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered '15/Apr/2021 12:37'	(b) (4) System	15 Apr 2021 19:37:11

US3142252

Folder: SAE USA-US064-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:20:38

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)	21 Apr 2021 20:34:34
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:39:30
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 19:37:11