

US3142043 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:00:33

All time stamps listed in this document are displayed in GMT

US3142043

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

[Participant ID](#)

US3142043

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

US3142043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3142043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
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 19:08:25

Generated On: 11 Aug 2021 22:00:33

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3142043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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 19:08:26

Generated On: 11 Aug 2021 22:00:33

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	BILATERAL NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
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 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	BILATERAL ASTIGMATISM
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
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 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	SEASONAL ALLERGIES
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)	_____

US3142043

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	URINARY TRACT INFECTIONS
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3142043

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Condition	HEART BURN
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)	_____

US3142043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:41 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 10:41
Height (<i>xxx.x</i>)	67.5 in
Weight (<i>xxx.x</i>)	191.6 lb
BMI (<i>xxx.x</i>)	29.62769 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 19:08:26

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 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 19:08:25

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*) 1 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 2009

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 19:08:26

Generated On: 11 Aug 2021 22:00:33

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 19:08:26

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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 19:08:27

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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 19:08:27

Generated On: 11 Aug 2021 22:00:33

What was the date of randomization? (dd MMM yyyy) 01 AUG 2020

What was the participant's randomization number? 100542

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 19:08:27

Generated On: 11 Aug 2021 22:00:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 AUG 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 10:41
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 AUG 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 12:06
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 01 AUG 2020

What was the treatment time? (00:00-23:59) 11:37 (24 HR)

Treatment Date and Time (derived) 01 AUG 2020 11:37

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 19:08:27

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 AUG 2020

Collection time (00:00-23:59)

11:24 (24 HR)

Collection date and time (derived)

01 AUG 2020 11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)			1 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	1 AUG 2020 11:24
Nasopharyngeal Swab 2	Yes	11:24	1 AUG 2020 11:24

US3142043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:27

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

01 AUG 2020 12:08

PC Open Date & Time

01 AUG 2020 11:57

PC Close Date & Time

01 AUG 2020 14:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 AUG 2020 15:22

PC Close Date & Time

02 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 18:39

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 23:01

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 16:59

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 06 AUG 2020 09:57

PC Open Date & Time 05 AUG 2020 12:00

PC Close Date & Time 06 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 08:40

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:09

PC Open Date & Time

01 AUG 2020 11:57

PC Close Date & Time

01 AUG 2020 14:27

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 AUG 2020 15:22

PC Close Date & Time

02 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 11:50

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 16:54

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 09:57

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 6
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 08:41

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 12:10
PC Open Date & Time	01 AUG 2020 11:57
PC Close Date & Time	01 AUG 2020 14:27

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 AUG 2020 15:22

PC Close Date & Time

02 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

Yes ☐

PC Time stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2602

EAB) (1725)

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 11:51
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 16:54
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2602

EAB) (1725)

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 10:02
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

60 of 2602

EAB) (1725)

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2602

EAB) (1725)

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 08:41
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3142043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	15:51 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 15:51
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	107 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	16:44 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 16:44
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 SEP 2020

What was the treatment time? (00:00-23:59) 16:14 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 16:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3142043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	16:01 (24 HR)
Collection date and time (derived)	1 SEP 2020 16:01

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:56	1 SEP 2020 15:56
Nasopharyngeal Swab 2	Yes	15:56	1 SEP 2020 15:56

US3142043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:28

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:46

PC Open Date & Time

01 SEP 2020 16:34

PC Close Date & Time

01 SEP 2020 19:04

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 01 SEP 2020 19:59

PC Close Date & Time 02 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 04 SEP 2020 12:22

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 14:55

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 6

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

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

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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.

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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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 15:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 07 SEP 2020 12:17

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

01 SEP 2020 16:46

PC Open Date & Time

01 SEP 2020 16:34

PC Close Date & Time

01 SEP 2020 19:04

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 19:59

PC Close Date & Time

02 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:40

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 14:55

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 15:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 16:47
PC Open Date & Time	01 SEP 2020 16:34
PC Close Date & Time	01 SEP 2020 19:04

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 19:59

PC Close Date & Time

02 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:23
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 14:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:17
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3142043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT3

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 16:24
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3142043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:29

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

16:32 (24 HR)

Collection date and time (derived)

28 SEP 2020 16:32

US3142043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:29

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 20:51:27

Patient Cloud Open Date & Time

01 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 00:50:27

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 02:29:29

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 11:32:09

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 NOV 2020 07:04:38
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 13:01:52

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 113
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"/>

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	19 NOV 2020 07:14:17
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:46:39
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	30 NOV 2020 10:57:13
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 06:55:50

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 06:06:46

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 07:23:24

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 08:13:06

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 06:44:05

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 05:50:37
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 09:42:55

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	27 JAN 2021 20:03:12
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 07:54:20

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 06:27:34
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 06:34:31
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 06:04:03

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 06:10:21
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 MAR 2021 08:27:24
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 07:29:10
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 16:13:34
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

12 APR 2021 07:03:32

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 07:27:51

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 06:03:39

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	03 MAY 2021 06:28:56
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 362

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 369

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 432

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 439

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 565

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

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

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

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

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

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

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 ☐

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 586

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 642

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 656

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 698

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 705

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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08 JUL 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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11 JUL 2022 00:01

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15 JUL 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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18 JUL 2022 00:01

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22 JUL 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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25 JUL 2022 00:01

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29 JUL 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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01 AUG 2022 00:01

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05 AUG 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

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12 AUG 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 747

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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15 AUG 2022 00:01

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19 AUG 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

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26 AUG 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 761

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

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02 SEP 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

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09 SEP 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

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12 SEP 2022 00:01

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16 SEP 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3142043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:00:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 06:04:15

US3142043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PT STARTED TAKING
HYDROCHLOROTHAZIDE ONCE
A DAY FOR HB 25MG

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3142043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3142043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

13:24 (24 HR)

Collection date and time (derived)

09 MAR 2021 13:24

US3142043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:47

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:24

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Date of Contact	02 DEC 2020
Time of Contact	13:00
Date and Time of Contact (derived)	02 DEC 2020 13:00
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>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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"/>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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"/>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 DEC 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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US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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"/>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 DEC 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 DEC 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
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 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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Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 DEC 2020
------	-------------

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

O2 Saturation	92 %
---------------	------

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 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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
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 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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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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"/>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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 02 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	89 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Symptom Day

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 19:08:18

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (13)

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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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	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 DEC 2020
------	-------------

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

O2 Saturation	91 %
---------------	------

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

Temperature	97.4 F
-------------	--------

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

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

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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

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Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:08:18

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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 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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

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Generated On: 11 Aug 2021 22:00:33

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

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Form: Symptom Log (16)

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Generated On: 11 Aug 2021 22:00:33

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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Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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 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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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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"/>

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Date of Visit 02 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 02 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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 02 DEC 2020
End Date 15 DEC 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 _____

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 DEC 2020
Day 5	Yes	06 DEC 2020
Day 7	Yes	09 DEC 2020
Day 9	Yes	11 DEC 2020
Day 14	Yes	16 DEC 2020
Day 21	Yes	23 DEC 2020
Day 28	No	

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 19:08:20

Generated On: 11 Aug 2021 22:00:33

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	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SICKD1

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 DEC 2020
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	02 DEC 2020 13:01
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 DEC 2020

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

US3142043

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 DEC 2020

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:38:44

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SICKD1

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 02:38:44

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 DEC 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	02 DEC 2020 10:44
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 02:38:44

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 DEC 2020

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

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:38:44

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 JAN 2021
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 10:44
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 JAN 2021

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

US3142043

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 JAN 2021

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3142043

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:00:33

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3142043

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

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

Visit date (dd MMM yyyy)	9 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3142043

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 02:38:44

Generated On: 11 Aug 2021 22:00:33

Date of updated informed consent (<i>dd MMM yyyy</i>)	7 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	07 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3142043

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

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

US3142043

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 13:12
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 14:01
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3142043

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 MAR 2021

What was the treatment time? (00:00-23:59) 13:31 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 13:31

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

What was the frequency of the study treatment dosing? ONCE

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

US3142043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	13:24 (24 HR)
Collection date and time (derived)	9 MAR 2021 13:24

US3142043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00 - 23:59)	13:25
Collection Date and Time (derived)	9 MAR 2021 13:25

US3142043

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:25

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 APR 2021
Time of assessment (00:00-23:59)	08:53 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 08:53
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	TEMPORAL83
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 APR 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 09:59
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3142043

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 APR 2021

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

US3142043

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 19:08:22

Generated On: 11 Aug 2021 22:00:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 01 APR 2021

What was the treatment time? (00:00-23:59) 09:29 (24 HR)

Treatment Date and Time (derived) 01 APR 2021 09:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3142043

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 19:08:21

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

AEID	USA-US064-2021-MRNA-1273-P30 1000005
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	30 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)	12 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

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

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT DIAGNOSED WITH HYPERTENSION AND WAS PRESCRIBED HYDROCHLORTHIAZIDE PER DAY 179 PHONE VISIT
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	
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US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Name of Medication HYDROCHLOROTHAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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)

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 19:08:18

Generated On: 11 Aug 2021 22:00:33

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3142043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:00:33

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3142043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:00:33

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

SAEID	USA-US064-2021-MRNA-1273-P301000005
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

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

SAEID	USA-US064-2021-MRNA-1273-P301000005
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)	22/JAN/2021 19:21
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

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 19:08:23

Generated On: 11 Aug 2021 22:00:33

SAEID	USA-US064-2021-MRNA-1273-P301000005
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)	02/MAR/2021 14:38
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.	True

Audit

US3142043 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142043

Form: Participant Creation

Generated On: 11 Aug 2021 22:00:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'US3142043'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 16:19:11

US3142043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:28
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:43:56

US3142043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:30
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 16:19:12

US3142043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:32
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:43:56

US3142043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'SCRN'	System	01 Aug 2020 16:43:56

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:42
User entered '(b) (6)1964'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 16:19:13

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:19:44
User entered '55'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'YEARS'	System	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '55'	System	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:45
User entered 'Female (F)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:19:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:19:49
User entered 'l'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:19:57
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:20:06
User entered '0'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:12
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:14
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:16
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:19
User entered empty.	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:21
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:33

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:23
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:53:58

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:33
User entered '01 Aug 2020'	Shelby Pickle (b) (4)	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Aug 2020'	System	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2020'	System	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Un-verified.	(b) (4)	
	Meghan York (b) (4)	09 Dec 2020 22:54:57
	(b) (4)	
User entered 'Amendment 2 (2)' reason for change:	Meghan York (b) (4)	09 Dec 2020 22:54:57
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:37
User entered 'Amendment 1 (1)'	Shelby Pickle (b) (4)	01 Aug 2020 16:44:10
	(b) (4)	

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:47
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:50
User entered empty.	Shelby Pickle (b) (4)	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:20:54
User entered empty.	Shelby Pickle (b) (4)	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:20:57
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:10

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:21:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 16:19:12

US3142043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1'	System	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:00:33

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:21:25
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:00:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:21:34
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Aug 2020 15:54:04

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:01:32
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:38:47
Data point term sent to Coder	System	01 Oct 2020 16:37:11
Query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:36:52
Coding entries removed.	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:36:48
User entered 'bilateral NEARSIGHTED' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:36:48
User opened query 'Per DM CLR: Please specify the laterality of eye that is NEARSIGHTED. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:53:57
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:56:22
Data point term sent to Coder	System	14 Aug 2020 15:55:31
User entered 'nearsighted'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:05
User entered 'UN UNK 1969'	Meghan York (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:06
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:08
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:10
User entered empty.	Meghan York (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:12
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 1969'	System	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1969'	System	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:54:43

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please specify the eye laterality of ASTIGMATISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:02:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:38:47
Data point term sent to Coder	System	01 Oct 2020 16:37:12
Query 'Per DM CLR: Please specify the eye laterality of ASTIGMATISM. Review and update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:37:10
Coding entries removed.	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:37:05
User entered 'bilateral ASTIGMATISM' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:37:05
User opened query 'Per DM CLR: Please specify the eye laterality of ASTIGMATISM. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:54:13
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:56:22
Data point term sent to Coder	System	14 Aug 2020 15:55:31
User entered 'astigmatism'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:22
User entered 'UN UNK 1969'	Meghan York (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:24
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:22:26
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:29
User entered empty.	Meghan York (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:33
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 1969'	System	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1969'	System	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:55:03

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:40
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)	14 Aug 2020 15:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 15:56:22
Data point term sent to Coder	System	14 Aug 2020 15:55:32
User entered 'seasonal allergies'	Meghan York (b) (4)	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:43
User entered 'UN UNK 1984'	Meghan York (b) (4)	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:45
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:22:48
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:50
User entered empty.	Meghan York (b) (4)	14 Aug 2020 15:55:28

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:22:53
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 1984'	System	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1984'	System	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 15:55:28

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:23:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 15:58:20
Data point term sent to Coder	System	14 Aug 2020 15:56:37
User entered 'urinary tract infections'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:23:01
User entered 'UN UNK 1990'	Meghan York (b) (4) (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:03
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:05
User entered 'No (N)'	Meghan York (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:07
User entered 'UN UNK 1990'	Meghan York (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:09
User entered '0'	Meghan York (b) (4)	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 1990'	System	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1990'	System	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 1990'	System	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1990'	System	14 Aug 2020 15:55:59

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:02:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:02:19
Data point term sent to Coder	System	14 Aug 2020 16:00:53
User entered 'hypercholesterolemia'	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:26
User entered 'UN UNK 2010'	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:27
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:29
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:31
User entered empty.	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:32
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2010'	System	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2010'	System	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:00:23

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please specify the location of ECZEMA. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify the location of ECZEMA. Review and update Med History eCRF as appropriate. ' answered with 'patient indicated intermittent eczema in multiple locations ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:03:52
User opened query 'Per DM CLR: Please specify the location of ECZEMA. Review and update Med History eCRF as appropriate. ' (Site from DM).	Meghan York (b) (4)	01 Oct 2020 16:38:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4), (b) (6)	01 Sep 2020 07:54:45
Data point term sent to Coder	Coder Import (b) (4)	14 Aug 2020 16:02:20
User entered 'eczema'	(b) (4)	
	Coder Import (b) (4)	14 Aug 2020 16:02:20
	(b) (4)	
	System	14 Aug 2020 16:01:53
	Meghan York (b) (4)	14 Aug 2020 16:00:55
	(b) (4)	

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:41
User entered 'UN UNK 2015'	Meghan York (b) (4)	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:49
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:50
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:23:52
User entered empty.	Meghan York (b) (4)	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:23:56
User entered '0'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2015'	System	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2015'	System	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:00:55

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:24:03
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:04:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:04:25
Data point term sent to Coder	System	14 Aug 2020 16:02:54
User entered 'post menopausal'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:05
User entered 'UN UNK 2010'	Meghan York (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:07
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:24:10
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:12
User entered empty.	Meghan York (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:14
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2010'	System	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2010'	System	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	14 Aug 2020 16:02:34

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please specify the location and/or type of SHINGLES. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:04:20
Query 'Per DM CLR: Please specify the location and/or type of SHINGLES. Review and update Med History eCRF as appropriate. ' answered with 'location was not indicated ' (Site from DM).	Meghan York (b) (4)	01 Oct 2020 16:39:14
User opened query 'Per DM CLR: Please specify the location and/or type of SHINGLES. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:55:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:05:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:05:16
Data point term sent to Coder	System	14 Aug 2020 16:03:58
User entered 'shingles'	Meghan York (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:21
User entered 'UN UNK 2015'	Meghan York (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:24:23
User entered '0'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:24:26
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:27
User entered 'UN UNK 2015'	Meghan York (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:32
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2015'	System	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2015'	System	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2015'	System	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2015'	System	14 Aug 2020 16:03:17

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 16:04:35
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:41:50
Data point term sent to Coder	System	01 Oct 2020 16:40:16
Query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:39:55
Coding entries removed.	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:39:49
User entered 'BASAL CELL cancer' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	01 Oct 2020 16:39:49
User opened query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:55:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:14
Data point term sent to Coder	System	14 Aug 2020 16:03:59
User entered 'basal cell'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:37
User entered 'UN UNK 2017'	Meghan York (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:39
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:24:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:43
User entered 'UN UNK 2017'	Meghan York (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 04:24:48
User entered '0'	Meghan York (b) (4)	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2017'	System	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2017'	System	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2017'	System	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2017'	System	14 Aug 2020 16:03:52

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 18:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 18:08:52
Data point term sent to Coder	System	01 Mar 2021 18:08:03
User entered 'heart burn'	Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	01 Mar 2021 18:08:09
User entered 'UN Jan 2020' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 18:08:09
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	01 Mar 2021 18:07:58
User entered 'un Jan 2021'	Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Jill York (b) (4)	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'Jan 2020'	System	01 Mar 2021 18:08:09
User entered 'Jan 2021'	System	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '2020'	System	01 Mar 2021 18:08:09
User entered '2021'	System	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:00:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered empty.	System	01 Mar 2021 18:07:58

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10:41'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1 Aug 2020 10:41'	System	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '67.5' in	(b) (4)	
	Meghan York (b) (4)	14 Aug 2020 16:05:22
	(b) (4)	
DataPoint set to visible.	System	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '191.6' lb	(b) (4) Meghan York (b) (4)	14 Aug 2020 16:05:22
DataPoint set to visible.	(b) (4) System	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
Amendment Manager: User entered '29.62769'	System	16 Sep 2020 23:40:27
User entered '29.6'	System	14 Aug 2020 16:05:22
DataPoint set to visible.	System	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'kg/m2'	System	14 Aug 2020 16:05:22
DataPoint set to visible.	System	01 Aug 2020 16:44:15

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 02:26:03
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:25
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:17:46
User entered '98.7' F	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty; reason for change Data Entry Error	(b) (4) Meghan York (b) (4)	25 Sep 2020 17:12:25
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	25 Sep 2020 17:12:25
	(b) (4)	
User entered 'temporal'	Meghan York (b) (4)	14 Aug 2020 16:05:22
	(b) (4)	

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:25
User entered '69'	Meghan York (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'bpm'	System	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:25
User entered '16'	Meghan York (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'breaths/min'	System	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:25
User entered '137'	Meghan York (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:25
User entered '86'	Meghan York (b) (4)	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:05:22

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07

US3142043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07

US3142043

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:05:31

US3142043

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:09:41
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 19:52:26
User entered '1 Aug 2020'	Meghan York (b) (4)	14 Aug 2020 16:05:31
	(b) (4)	

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'UN UNK 2009'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:33

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:06:43

US3142043

Folder: Screening

Form: Risk of Exposure

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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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)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'I'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Shelby Pickle (b) (4) (b) (4)	01 Aug 2020 16:44:51

US3142043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:04

US3142043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:04

US3142043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Clinic (Clinic)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:04

US3142043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'VISIT1'	System	14 Aug 2020 16:07:04

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '01 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 17:29:11

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:37:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 17:29:11
User entered '100542' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 17:29:11

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 17:29:11

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:22

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:22

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:22

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:22

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:07:22

US3142043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:33

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
DataPoint set to visible.	System	09 Dec 2020 22:54:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 03:17:18

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:46
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:38:46
User entered '67.5' in	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:46
User entered '191.6' lb	Meghan York (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:46
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:38:46
User entered '67.5' in	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:46
User entered '191.6' lb	Meghan York (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10:41'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1 Aug 2020 10:41'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '98.7' F	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'temporal'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '69'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'bpm'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'breaths/min'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '137'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '86'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:30:54
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	25 Sep 2020 17:12:46
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:38:46
User entered '67.5' in	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:12:46
User entered '191.6' lb	Meghan York (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 23:48:13
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 16:10:35
User entered '12:06'	Meghan York (b) (4)	14 Aug 2020 16:10:35
	(b) (4)	

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1 Aug 2020 12:06'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97.7' F	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'temporal'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '75'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'bpm'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '18'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'breaths/min'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '154'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '94'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'mmHg'	System	14 Aug 2020 16:10:35

US3142043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Sep 2020 17:13:03
User entered 'Yes (Y)'	Meghan York (b) (4)	14 Aug 2020 16:10:56

US3142043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	25 Sep 2020 17:13:03
	(b) (4)	
User entered '1 Aug 2020'	Meghan York (b) (4)	14 Aug 2020 16:10:56
	(b) (4)	

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '01 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '11:37'	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '01 Aug 2020 11:37'	System	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Meghan York (b) (4) (b) (4)	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'ONCE'	System	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 17:44:36

US3142043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:55:24

US3142043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '01 Aug 2020'	(b) (4), (b) (6)	05 Aug 2020 20:55:24

US3142043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '11:24'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:55:24

US3142043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '01 Aug 2020 11:24'	System	05 Aug 2020 20:55:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:00:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Aug 2020'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '11:24'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1 Aug 2020 11:24'	System	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '11:24'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1 Aug 2020 11:24'	System	14 Aug 2020 16:11:24

US3142043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	14 Aug 2020 16:11:28

US3142043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1'	System	14 Aug 2020 16:11:28

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:08:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ef5569a8-e929-49be-8d9f-69c5080620e9'	System	01 Aug 2020 18:08:54
User entered 'Yes (Y)'	System	01 Aug 2020 18:08:54

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:08:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ef5569a8-e929-49be-8d9f-69c5080620e9'	System	01 Aug 2020 18:08:54
User entered '97.7'	System	01 Aug 2020 18:08:54

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:08:46', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ef5569a8-e929-49be-8d9f-69c5080620e9'	System	01 Aug 2020 18:08:54
User entered 'No (N)'	System	01 Aug 2020 18:08:54

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:08:52', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ef5569a8-e929-49be-8d9f-69c5080620e9'	System	01 Aug 2020 18:08:54
User entered '01 Aug 2020 12:08'	System	01 Aug 2020 18:08:54

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 11:57'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 14:27'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 15:22'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 2'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-02T18:39:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '86996e3c-6efa-439a-8892-bdb41c0e61ea'	System	03 Aug 2020 00:39:55
User entered 'Yes (Y)'	System	03 Aug 2020 00:39:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-02T18:39:44', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '86996e3c-6efa-439a-8892-bdb41c0e61ea'	System	03 Aug 2020 00:39:55
User entered '96.6'	System	03 Aug 2020 00:39:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-02T18:39:48', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '86996e3c-6efa-439a-8892-bdb41c0e61ea'	System	03 Aug 2020 00:39:55
User entered 'No (N)'	System	03 Aug 2020 00:39:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-02T18:39:52', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '86996e3c-6efa-439a-8892-bdb41c0e61ea'	System	03 Aug 2020 00:39:55
User entered '02 Aug 2020 18:39'	System	03 Aug 2020 00:39:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 3'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-03T22:59:41', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '93f4a128-bd90-41c2-a807-23cda12f70a6'	System	04 Aug 2020 17:50:29
User entered 'Yes (Y)'	System	04 Aug 2020 17:50:29

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-03T23:00:43', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '93f4a128-bd90-41c2-a807-23cda12f70a6'	System	04 Aug 2020 17:50:29
User entered '95.5'	System	04 Aug 2020 17:50:29

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-03T23:00:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '93f4a128-bd90-41c2-a807-23cda12f70a6'	System	04 Aug 2020 17:50:29
User entered 'No (N)'	System	04 Aug 2020 17:50:29

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-03T23:01:02', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '93f4a128-bd90-41c2-a807-23cda12f70a6'	System	04 Aug 2020 17:50:29
User entered '03 Aug 2020 23:01'	System	04 Aug 2020 17:50:29

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 4'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:59:24', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ec8f836-8141-4c52-8abe-29b12b5ebe20'	System	04 Aug 2020 22:59:39
User entered 'Yes (Y)'	System	04 Aug 2020 22:59:39

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:59:30', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ec8f836-8141-4c52-8abe-29b12b5ebe20'	System	04 Aug 2020 22:59:39
User entered '98.4'	System	04 Aug 2020 22:59:39

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:59:33', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ec8f836-8141-4c52-8abe-29b12b5ebe20'	System	04 Aug 2020 22:59:39
User entered 'No (N)'	System	04 Aug 2020 22:59:39

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:59:35', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ec8f836-8141-4c52-8abe-29b12b5ebe20'	System	04 Aug 2020 22:59:39
User entered '04 Aug 2020 16:59'	System	04 Aug 2020 22:59:39

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 5'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:01', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '7691bf59-5a09-49d7-98ec-524d9e86a03c'	System	06 Aug 2020 15:58:45
User entered 'No (N)'	System	06 Aug 2020 15:58:45

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:04', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '7691bf59-5a09-49d7-98ec-524d9e86a03c'	System	06 Aug 2020 15:58:45
User entered 'No (N)'	System	06 Aug 2020 15:58:45

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:07', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '7691bf59-5a09-49d7-98ec-524d9e86a03c'	System	06 Aug 2020 15:58:45
User entered '06 Aug 2020 09:57'	System	06 Aug 2020 15:58:45

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 6'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 7'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '926dfc49-c507-486c-b0c4-7bafd94ae0cf'	System	08 Aug 2020 14:40:55
User entered 'Yes (Y)'	System	08 Aug 2020 14:40:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:46', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '926dfc49-c507-486c-b0c4-7bafd94ae0cf'	System	08 Aug 2020 14:40:55
User entered '97.9'	System	08 Aug 2020 14:40:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:49', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '926dfc49-c507-486c-b0c4-7bafd94ae0cf'	System	08 Aug 2020 14:40:55
User entered 'No (N)'	System	08 Aug 2020 14:40:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:51', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '926dfc49-c507-486c-b0c4-7bafd94ae0cf'	System	08 Aug 2020 14:40:55
User entered '08 Aug 2020 08:40'	System	08 Aug 2020 14:40:55

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:26', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8feca2bb-800f-435c-ae51-42a98b55bb52'	System	01 Aug 2020 18:09:50
User entered 'None (1)'	System	01 Aug 2020 18:09:50

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:32', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8feca2bb-800f-435c-ae51-42a98b55bb52'	System	01 Aug 2020 18:09:50
User entered 'No (N)'	System	01 Aug 2020 18:09:50

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:35', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8feca2bb-800f-435c-ae51-42a98b55bb52'	System	01 Aug 2020 18:09:50
User entered 'No (N)'	System	01 Aug 2020 18:09:50

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:41', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8feca2bb-800f-435c-ae51-42a98b55bb52'	System	01 Aug 2020 18:09:50
User entered 'None (1)'	System	01 Aug 2020 18:09:50

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:47', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8feca2bb-800f-435c-ae51-42a98b55bb52'	System	01 Aug 2020 18:09:50
User entered '01 Aug 2020 12:09'	System	01 Aug 2020 18:09:50

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 11:57'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 14:27'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 15:22'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 2'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 3'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:36', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '64c69148-8a71-44e7-a445-155d3b67d594'	System	04 Aug 2020 17:51:06
User entered 'None (1)'	System	04 Aug 2020 17:51:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '64c69148-8a71-44e7-a445-155d3b67d594'	System	04 Aug 2020 17:51:06
User entered 'No (N)'	System	04 Aug 2020 17:51:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:42', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '64c69148-8a71-44e7-a445-155d3b67d594'	System	04 Aug 2020 17:51:06
User entered 'No (N)'	System	04 Aug 2020 17:51:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:45', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '64c69148-8a71-44e7-a445-155d3b67d594'	System	04 Aug 2020 17:51:06
User entered 'None (1)'	System	04 Aug 2020 17:51:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:48', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '64c69148-8a71-44e7-a445-155d3b67d594'	System	04 Aug 2020 17:51:06
User entered '04 Aug 2020 11:50'	System	04 Aug 2020 17:51:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 4'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:04', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b9fb6690-5495-4c61-83c2-b5983ddee677'	System	04 Aug 2020 22:54:21
User entered 'None (1)'	System	04 Aug 2020 22:54:21

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:07', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b9fb6690-5495-4c61-83c2-b5983ddee677'	System	04 Aug 2020 22:54:21
User entered 'No (N)'	System	04 Aug 2020 22:54:21

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b9fb6690-5495-4c61-83c2-b5983ddee677'	System	04 Aug 2020 22:54:21
User entered 'No (N)'	System	04 Aug 2020 22:54:21

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:12', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b9fb6690-5495-4c61-83c2-b5983ddee677'	System	04 Aug 2020 22:54:21
User entered 'None (1)'	System	04 Aug 2020 22:54:21

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:18', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b9fb6690-5495-4c61-83c2-b5983ddee677'	System	04 Aug 2020 22:54:21
User entered '04 Aug 2020 16:54'	System	04 Aug 2020 22:54:21

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 5'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'f6bc371e-ef01-4b07-9074-6bac4eee6ac0'	System	06 Aug 2020 15:58:57
User entered 'None (1)'	System	06 Aug 2020 15:58:57

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'f6bc371e-ef01-4b07-9074-6bac4eee6ac0'	System	06 Aug 2020 15:58:57
User entered 'No (N)'	System	06 Aug 2020 15:58:57

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:14', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'f6bc371e-ef01-4b07-9074-6bac4eee6ac0'	System	06 Aug 2020 15:58:57
User entered 'No (N)'	System	06 Aug 2020 15:58:57

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:16', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'f6bc371e-ef01-4b07-9074-6bac4eee6ac0'	System	06 Aug 2020 15:58:57
User entered 'None (1)'	System	06 Aug 2020 15:58:57

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:19', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'f6bc371e-ef01-4b07-9074-6bac4eee6ac0'	System	06 Aug 2020 15:58:57
User entered '06 Aug 2020 09:57'	System	06 Aug 2020 15:58:57

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 6'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 7'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:55', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '3e209760-490a-4442-9ed4-152ec327dfd0'	System	08 Aug 2020 14:41:06
User entered 'None (1)'	System	08 Aug 2020 14:41:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '3e209760-490a-4442-9ed4-152ec327dfd0'	System	08 Aug 2020 14:41:06
User entered 'No (N)'	System	08 Aug 2020 14:41:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:40:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '3e209760-490a-4442-9ed4-152ec327dfd0'	System	08 Aug 2020 14:41:06
User entered 'No (N)'	System	08 Aug 2020 14:41:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '3e209760-490a-4442-9ed4-152ec327dfd0'	System	08 Aug 2020 14:41:06
User entered 'None (1)'	System	08 Aug 2020 14:41:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:02', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '3e209760-490a-4442-9ed4-152ec327dfd0'	System	08 Aug 2020 14:41:06
User entered '08 Aug 2020 08:41'	System	08 Aug 2020 14:41:06

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:54', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered 'None (0)'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:09:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered 'None (0)'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:03', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered 'None (0)'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e' User entered 'None (0)'	System	01 Aug 2020 18:10:32
	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:15', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e' User entered 'None (0)'	System	01 Aug 2020 18:10:32
	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:19', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered 'None (0)'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:26', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered 'No (N)'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-01T12:10:29', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2ce6324b-f296-4920-8314-5d785140732e'	System	01 Aug 2020 18:10:32
User entered '01 Aug 2020 12:10'	System	01 Aug 2020 18:10:32

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 11:57'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 14:27'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Aug 2020 15:22'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 2'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 3'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:53', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:55', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:50:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:51:01', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:51:03', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'None (0)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:51:06', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered 'No (N)'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T11:51:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0d83040f-851a-4864-bd1f-fe7c256676af'	System	04 Aug 2020 17:51:14
User entered '04 Aug 2020 11:51'	System	04 Aug 2020 17:51:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 4'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:21', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:25', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:27', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:29', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:31', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'None (0)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered 'No (N)'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-04T16:54:37', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1dce9af4-22e2-4baa-9a1c-ab006e3f309c'	System	04 Aug 2020 22:54:41
User entered '04 Aug 2020 16:54'	System	04 Aug 2020 22:54:41

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 5'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:22', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T09:57:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:12', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'None (0)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:17', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered 'No (N)'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-06T10:02:19', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ff4ae54c-f14c-4294-b6a6-73d345a18bf5'	System	06 Aug 2020 16:03:59
User entered '06 Aug 2020 10:02'	System	06 Aug 2020 16:03:59

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 6'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 7'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:06', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:07', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:11', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'None (0)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:15', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered 'No (N)'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea250818aca2ac82)', Time: '2020-08-08T08:41:18', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'fe6cba0d-1c0e-41f4-a760-eb44f736f741'	System	08 Aug 2020 14:41:21
User entered '08 Aug 2020 08:41'	System	08 Aug 2020 14:41:21

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 17:44:36

US3142043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	20 Aug 2020 19:41:47

US3142043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '8 Aug 2020'	(b) (4)	
	Dalia Jeronimo (b) (4)	20 Aug 2020 19:41:47
	(b) (4)	

US3142043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	20 Aug 2020 19:41:47

US3142043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Dalia Jeronimo (b) (4)	20 Aug 2020 19:41:47
	(b) (4)	

US3142043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	20 Aug 2020 19:41:56

US3142043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1'	System	20 Aug 2020 19:41:56

US3142043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3142043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '17 Aug 2020'	Jami Wagner (b) (4)	24 Aug 2020 14:15:39

US3142043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3142043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:15:39

US3142043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	24 Aug 2020 14:15:49

US3142043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered 'I'	System	24 Aug 2020 14:15:49

US3142043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:40:16

US3142043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 21:33:55
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct' (Site from System).	Jami Wagner (b) (4)	03 Sep 2020 01:26:23
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 02:40:16
User entered '26 Aug 2020'	Jami Wagner (b) (4)	31 Aug 2020 02:40:16

US3142043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:40:16

US3142043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:40:16

US3142043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	31 Aug 2020 02:40:26

US3142043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:07
User entered '1'	System	31 Aug 2020 02:40:26

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4) (b) (4)	14 Sep 2020 19:52:26

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Site response noted. However the collection date 01SEP2020 is not updated in EDC. Please update sample 01sep2020 details on page Immunogenicity Assessment at visit 2 day 29.' (Site from DM).	(b) (4)	09 Dec 2020 06:52:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Site response noted. However the collection date 01SEP2020 is not updated in EDC. Please update sample 01sep2020 details on page Immunogenicity Assessment at visit 2 day 29.' answered with 'now entered into EDC' (Site from DM).	Meghan York (b) (4)	01 Dec 2020 19:23:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Site response noted. However the collection date 01SEP2020 is not updated in EDC. Please update sample 01sep2020 details on page Immunogenicity Assessment at visit 2 day 29.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:39:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is reported under Unscheduled visit in PPD Central lab, however the collection date 01SEP2020 is not updated in EDC. Please confirm the correct visit and date collected the sample 01sep2020 and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:37:31
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is reported under Unscheduled visit in PPD Central lab, however the collection date 01SEP2020 is not updated in EDC. Please confirm the correct visit and date collected the sample 01sep2020 and update accordingly.' answered with 'Unscheduled lab kit was used for this visit due to lack of supplies.' (Site from DM).	Meghan York (b) (4)	10 Nov 2020 21:34:29

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is reported under Unscheduled visit in PPD Central lab, however the collection date 01SEP2020 is not updated in EDC. Please confirm the correct visit and date collected the sample 01sep2020 and update accordingly.' (Site from DM). User entered '1 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 16:46:30
	Dalia Jeronimo (b) (4)	14 Sep 2020 19:52:26
	(b) (4)	

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Clinic (Clinic)'	(b) (4) Dalia Jeronimo (b) (4) (b) (4)	14 Sep 2020 19:52:26

US3142043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'VISIT2'	System	14 Sep 2020 19:52:26

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User accepted default value 'Pre-Dose (PREDOSE)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34
	(b) (4)	

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '01 Sep 2020'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '15:51'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '01 Sep 2020 15:51'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97.6' F	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Temporal'	(b) (4) Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '84'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'bpm'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'breaths/min'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '140'	(b) (4) Dalia Jeronimo (b) (4) (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	16 Sep 2020 23:40:27
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		14 Sep 2020 19:54:34
User entered '107'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34
	(b) (4)	

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User accepted default value 'Post-Dose (POSTDOSE)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Sep 2020'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16:44'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '1 Sep 2020 16:44'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97.3' F	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Temporal'	(b) (4) Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '75'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'bpm'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '14'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'breaths/min'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '152'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '91'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	14 Sep 2020 19:54:34

US3142043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:55:42

US3142043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Sep 2020'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:55:42

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:15:46
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'This assesment was done on day 29 visit. Unscheduled lab kit was used due to lack of supplies ' (Site from DM).	Meghan York (b) (4) (b) (4)	27 Oct 2020 19:11:39
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 01SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 02:47:29
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Meghan York (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '1 Sep 2020'	(b) (4) Meghan York (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16:14'	(b) (4) Meghan York (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '1 Sep 2020 16:14'	System	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Meghan York (b) (4)	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'ONCE'	System	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 22:32:36

US3142043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	01 Dec 2020 19:23:21

US3142043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however 1SEP2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:39:37
' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however 1SEP2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.	Meghan York (b) (4) (b) (4)	09 Dec 2020 21:46:21
' answered with 'Unscheduled lab kit was used due to lack of supplies ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however 1SEP2020 is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct visit and update EDC or PPD Central lab.	(b) (4), (b) (6)	07 Dec 2020 13:14:35
' (Site from DM). User entered '1 Sep 2020'	Meghan York (b) (4) (b) (4)	01 Dec 2020 19:23:21

US3142043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16:01'	(b) (4) Meghan York (b) (4)	01 Dec 2020 19:23:21

US3142043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '1 Sep 2020 16:01'	System	01 Dec 2020 19:23:21

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:23:17
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' answered with 'Unschduled lab kit was used for this visit due to lack of supplies. ' (Site from DM).	Meghan York (b) (4) (b) (4)	21 Oct 2020 14:44:11
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:53:23
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' canceled (Site from DM).		20 Oct 2020 11:53:12
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 01SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).		20 Oct 2020 11:47:34
User entered '1 Sep 2020'	Dalia Jeronimo (b) (4) (b) (4)	14 Sep 2020 19:56:10

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EAB) (1725)

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '15:56'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '1 Sep 2020 15:56'	System	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '15:56'	Dalia Jeronimo (b) (4)	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '1 Sep 2020 15:56'	System	14 Sep 2020 19:56:10

US3142043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:11

US3142043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	14 Sep 2020 14:40:11

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5b3f57e1-e589-4fc6-8a08-4a8a69adb867'	System	01 Sep 2020 22:46:35
User entered 'Yes (Y)'	System	01 Sep 2020 22:46:35

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5b3f57e1-e589-4fc6-8a08-4a8a69adb867' User entered '97.3'	System	01 Sep 2020 22:46:35
	System	01 Sep 2020 22:46:35

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:26', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5b3f57e1-e589-4fc6-8a08-4a8a69adb867'	System	01 Sep 2020 22:46:35
User entered 'No (N)'	System	01 Sep 2020 22:46:35

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:30', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5b3f57e1-e589-4fc6-8a08-4a8a69adb867'	System	01 Sep 2020 22:46:35
User entered '01 Sep 2020 16:46'	System	01 Sep 2020 22:46:35

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 2'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 3'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:43:11', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '13f4ddfd-7631-4875-a71f-7a3820717944'	System	04 Sep 2020 01:44:49
User entered 'Yes (Y)'	System	04 Sep 2020 01:44:49

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:44:42', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '13f4ddfd-7631-4875-a71f-7a3820717944'	System	04 Sep 2020 01:44:49
User entered '97.3'	System	04 Sep 2020 01:44:49

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:44:45', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '13f4ddfd-7631-4875-a71f-7a3820717944'	System	04 Sep 2020 01:44:49
User entered 'No (N)'	System	04 Sep 2020 01:44:49

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:44:49', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '13f4ddfd-7631-4875-a71f-7a3820717944'	System	04 Sep 2020 01:44:49
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 01:44:49

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 4'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:29', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '59f69c5a-1a15-4961-bcd2-b9ee248f43d8'	System	04 Sep 2020 17:22:33
User entered 'No (N)'	System	04 Sep 2020 17:22:33

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:31', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '59f69c5a-1a15-4961-bcd2-b9ee248f43d8'	System	04 Sep 2020 17:22:33
User entered 'No (N)'	System	04 Sep 2020 17:22:33

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '59f69c5a-1a15-4961-bcd2-b9ee248f43d8'	System	04 Sep 2020 17:22:33
User entered '04 Sep 2020 12:22'	System	04 Sep 2020 17:22:33

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 5'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:20', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '30ef37d0-3ed4-407f-a840-b76ed72e1b13'	System	05 Sep 2020 19:55:34
User entered 'Yes (Y)'	System	05 Sep 2020 19:55:34

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:25', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '30ef37d0-3ed4-407f-a840-b76ed72e1b13'	System	05 Sep 2020 19:55:34
User entered '95.5'	System	05 Sep 2020 19:55:34

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:28', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '30ef37d0-3ed4-407f-a840-b76ed72e1b13'	System	05 Sep 2020 19:55:34
User entered 'No (N)'	System	05 Sep 2020 19:55:34

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:32', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '30ef37d0-3ed4-407f-a840-b76ed72e1b13'	System	05 Sep 2020 19:55:34
User entered '05 Sep 2020 14:55'	System	05 Sep 2020 19:55:34

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 6'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '53298d42-edbf-42df-9873-9f6b811994a2'	System	06 Sep 2020 20:56:50
User entered 'Yes (Y)'	System	06 Sep 2020 20:56:50

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:43', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '53298d42-edbf-42df-9873-9f6b811994a2'	System	06 Sep 2020 20:56:50
User entered '96.6'	System	06 Sep 2020 20:56:50

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:45', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '53298d42-edbf-42df-9873-9f6b811994a2'	System	06 Sep 2020 20:56:50
User entered 'No (N)'	System	06 Sep 2020 20:56:50

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:48', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '53298d42-edbf-42df-9873-9f6b811994a2'	System	06 Sep 2020 20:56:50
User entered '06 Sep 2020 15:56'	System	06 Sep 2020 20:56:50

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 7'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '32cb1c79-7f4a-4c31-94a1-a81e877e614c'	System	07 Sep 2020 17:17:15
User entered 'No (N)'	System	07 Sep 2020 17:17:15

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '32cb1c79-7f4a-4c31-94a1-a81e877e614c'	System	07 Sep 2020 17:17:15
User entered 'No (N)'	System	07 Sep 2020 17:17:15

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:15', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '32cb1c79-7f4a-4c31-94a1-a81e877e614c'	System	07 Sep 2020 17:17:15
User entered '07 Sep 2020 12:17'	System	07 Sep 2020 17:17:15

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '05258ac6-07a7-481e-ac50-8eb8afe54a91'	System	01 Sep 2020 22:46:49
User entered 'None (1)'	System	01 Sep 2020 22:46:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:36', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '05258ac6-07a7-481e-ac50-8eb8afe54a91'	System	01 Sep 2020 22:46:49
User entered 'No (N)'	System	01 Sep 2020 22:46:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '05258ac6-07a7-481e-ac50-8eb8afe54a91'	System	01 Sep 2020 22:46:49
User entered 'No (N)'	System	01 Sep 2020 22:46:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:41', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '05258ac6-07a7-481e-ac50-8eb8afe54a91'	System	01 Sep 2020 22:46:49
User entered 'None (1)'	System	01 Sep 2020 22:46:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:45', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '05258ac6-07a7-481e-ac50-8eb8afe54a91'	System	01 Sep 2020 22:46:49
User entered '01 Sep 2020 16:46'	System	01 Sep 2020 22:46:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 2'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 3'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:39:54', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '155a671b-ef12-4953-98fb-5ed528738cfb'	System	04 Sep 2020 01:40:07
User entered 'None (1)'	System	04 Sep 2020 01:40:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:39:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '155a671b-ef12-4953-98fb-5ed528738cfb'	System	04 Sep 2020 01:40:07
User entered 'No (N)'	System	04 Sep 2020 01:40:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:39:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '155a671b-ef12-4953-98fb-5ed528738cfb'	System	04 Sep 2020 01:40:07
User entered 'No (N)'	System	04 Sep 2020 01:40:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:01', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '155a671b-ef12-4953-98fb-5ed528738cfb'	System	04 Sep 2020 01:40:07
User entered 'None (1)'	System	04 Sep 2020 01:40:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:04', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '155a671b-ef12-4953-98fb-5ed528738cfb'	System	04 Sep 2020 01:40:07
User entered '03 Sep 2020 20:40'	System	04 Sep 2020 01:40:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 4'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:40', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a5c94655-0a09-4820-9e4f-ea4a0af1bf89'	System	04 Sep 2020 17:22:48
User entered 'None (1)'	System	04 Sep 2020 17:22:48

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:43', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a5c94655-0a09-4820-9e4f-ea4a0af1bf89'	System	04 Sep 2020 17:22:48
User entered 'No (N)'	System	04 Sep 2020 17:22:48

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:45', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a5c94655-0a09-4820-9e4f-ea4a0af1bf89'	System	04 Sep 2020 17:22:48
User entered 'No (N)'	System	04 Sep 2020 17:22:48

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:46', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a5c94655-0a09-4820-9e4f-ea4a0af1bf89'	System	04 Sep 2020 17:22:48
User entered 'None (1)'	System	04 Sep 2020 17:22:48

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:50', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a5c94655-0a09-4820-9e4f-ea4a0af1bf89'	System	04 Sep 2020 17:22:48
User entered '04 Sep 2020 12:22'	System	04 Sep 2020 17:22:48

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 5'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:36', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0c999fb6-c447-42d6-bcc8-c18ccd752b8a'	System	05 Sep 2020 19:55:49
User entered 'None (1)'	System	05 Sep 2020 19:55:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0c999fb6-c447-42d6-bcc8-c18ccd752b8a'	System	05 Sep 2020 19:55:49
User entered 'No (N)'	System	05 Sep 2020 19:55:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:40', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0c999fb6-c447-42d6-bcc8-c18ccd752b8a'	System	05 Sep 2020 19:55:49
User entered 'No (N)'	System	05 Sep 2020 19:55:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:44', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0c999fb6-c447-42d6-bcc8-c18ccd752b8a'	System	05 Sep 2020 19:55:49
User entered 'None (1)'	System	05 Sep 2020 19:55:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:47', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0c999fb6-c447-42d6-bcc8-c18ccd752b8a'	System	05 Sep 2020 19:55:49
User entered '05 Sep 2020 14:55'	System	05 Sep 2020 19:55:49

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 6'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ac5e7ed6-8cf5-493a-9151-30f67f143dc3'	System	06 Sep 2020 20:57:07
User entered 'None (1)'	System	06 Sep 2020 20:57:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:56:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ac5e7ed6-8cf5-493a-9151-30f67f143dc3'	System	06 Sep 2020 20:57:07
User entered 'No (N)'	System	06 Sep 2020 20:57:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ac5e7ed6-8cf5-493a-9151-30f67f143dc3'	System	06 Sep 2020 20:57:07
User entered 'No (N)'	System	06 Sep 2020 20:57:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:02', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ac5e7ed6-8cf5-493a-9151-30f67f143dc3'	System	06 Sep 2020 20:57:07
User entered 'None (1)'	System	06 Sep 2020 20:57:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:05', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ac5e7ed6-8cf5-493a-9151-30f67f143dc3'	System	06 Sep 2020 20:57:07
User entered '06 Sep 2020 15:57'	System	06 Sep 2020 20:57:07

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 7'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:18', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'cb27a465-b1d1-46d4-8002-c5ec32fa3feb'	System	07 Sep 2020 17:17:27
User entered 'None (1)'	System	07 Sep 2020 17:17:27

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:21', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'cb27a465-b1d1-46d4-8002-c5ec32fa3feb'	System	07 Sep 2020 17:17:27
User entered 'No (N)'	System	07 Sep 2020 17:17:27

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'cb27a465-b1d1-46d4-8002-c5ec32fa3feb'	System	07 Sep 2020 17:17:27
User entered 'No (N)'	System	07 Sep 2020 17:17:27

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:24', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'cb27a465-b1d1-46d4-8002-c5ec32fa3feb'	System	07 Sep 2020 17:17:27
User entered 'None (1)'	System	07 Sep 2020 17:17:27

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:27', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'cb27a465-b1d1-46d4-8002-c5ec32fa3feb'	System	07 Sep 2020 17:17:27
User entered '07 Sep 2020 12:17'	System	07 Sep 2020 17:17:27

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:48', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:50', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:51', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:53', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:54', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:56', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'None (0)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:46:58', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered 'No (N)'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-01T16:47:01', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ab573b89-c11a-4bda-8904-89a6ab70f437'	System	01 Sep 2020 22:47:06
User entered '01 Sep 2020 16:47'	System	01 Sep 2020 22:47:06

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 2'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 3'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:11', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:14', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:16', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:18', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:20', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'None (0)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:22', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered 'No (N)'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-03T20:40:25', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76b1db0f-4a15-48b1-8741-21619359a6a7'	System	04 Sep 2020 01:40:27
User entered '03 Sep 2020 20:40'	System	04 Sep 2020 01:40:27

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 4'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:54', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b'	System	04 Sep 2020 17:23:09
User entered 'None (0)'	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:56', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b' User entered 'None (0)'	System	04 Sep 2020 17:23:09
	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:22:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b' User entered 'None (0)'	System	04 Sep 2020 17:23:09
	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:23:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b' User entered 'None (0)'	System	04 Sep 2020 17:23:09
	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:23:02', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b' User entered 'None (0)'	System	04 Sep 2020 17:23:09
	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:23:04', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b'	System	04 Sep 2020 17:23:09
User entered 'None (0)'	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:23:07', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b'	System	04 Sep 2020 17:23:09
User entered 'No (N)'	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-04T12:23:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2899d1a6-61f8-44e1-a895-5c4ea39b376b' User entered '04 Sep 2020 12:23'	System	04 Sep 2020 17:23:09
	System	04 Sep 2020 17:23:09

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 5'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:50', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:51', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:53', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:55', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:56', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:57', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'None (0)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:55:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered 'No (N)'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-05T14:56:03', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '54b1b9d3-595d-475e-ae0d-bcc352efa77f'	System	05 Sep 2020 19:56:07
User entered '05 Sep 2020 14:56'	System	05 Sep 2020 19:56:07

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 6'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:11', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:14', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:16', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'None (0)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:17', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered 'No (N)'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-06T15:57:22', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'ad200255-3dcf-4529-959f-c8d44a3057c1'	System	06 Sep 2020 20:57:23
User entered '06 Sep 2020 15:57'	System	06 Sep 2020 20:57:23

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Sep 2020 22:32:36
User entered 'Day 7'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:31', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:33', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:36', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:41', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'None (0)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:43', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered 'No (N)'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-09-07T12:17:49', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'e204bc31-dd08-4922-82a2-3a260aae9f10'	System	07 Sep 2020 17:17:47
User entered '07 Sep 2020 12:17'	System	07 Sep 2020 17:17:47

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 22:32:36

US3142043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 22:32:36

US3142043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:30

US3142043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '11 Sep 2020'	Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:30

US3142043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:30

US3142043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:30

US3142043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Dalia Jeronimo (b) (4)	14 Sep 2020 14:40:35

US3142043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	14 Sep 2020 14:40:35

US3142043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	23 Sep 2020 21:22:17

US3142043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '18 Sep 2020'	Dalia Jeronimo (b) (4)	23 Sep 2020 21:22:17

US3142043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	23 Sep 2020 21:22:17

US3142043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Dalia Jeronimo (b) (4)	23 Sep 2020 21:22:17
	(b) (4)	

US3142043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	24 Sep 2020 15:19:51

US3142043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	24 Sep 2020 15:19:51

US3142043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	24 Sep 2020 15:20:06

US3142043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '23 Sep 2020'	Jami Wagner (b) (4)	24 Sep 2020 15:20:06

US3142043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	24 Sep 2020 15:20:06

US3142043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Jami Wagner (b) (4) (b) (4)	24 Sep 2020 15:20:06

US3142043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	24 Sep 2020 15:20:16

US3142043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	24 Sep 2020 15:20:16

US3142043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
Query 'Per GCL Lab Recon: GCL is reporting receiving a COVID PCR Swab dated 01Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Oct 2020 23:50:54
User opened query 'Per GCL Lab Recon: GCL is reporting receiving a COVID PCR Swab dated 01Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).		24 Oct 2020 02:38:46
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:28:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '28 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:28:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	29 Sep 2020 20:28:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'VISIT3'	System	29 Sep 2020 20:28:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '28 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '16:24'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '28 Sep 2020 16:24'	System	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '97.3' F	Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '83'	Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'bpm'	System	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '12'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'breaths/min'	System	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '133'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '95'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'mmHg'	System	29 Sep 2020 20:36:02

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52

US3142043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52

US3142043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:09

US3142043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '28 Sep 2020'	Shelby Pickle (b) (4)	29 Sep 2020 20:36:09

US3142043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	29 Sep 2020 20:36:37

US3142043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28 SEP 2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:02:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28 SEP 2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'unscheduled lab kit was used for this visit due to lack of supplies ' (Site from DM).	Meghan York (b) (4) (b) (4)	19 Oct 2020 15:26:52
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28 SEP 2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:45:17
User entered '28 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	29 Sep 2020 20:36:37

US3142043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16:32'	Shelby Pickle (b) (4)	29 Sep 2020 20:36:37

US3142043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered '28 Sep 2020 16:32'	System	29 Sep 2020 20:36:37

US3142043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	29 Sep 2020 20:36:42

US3142043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	29 Sep 2020 20:36:42

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 64'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-02T20:51:16', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2baa3189-34c8-4614-b6f4-056ba517c112'	System	03 Oct 2020 02:51:39
User entered 'No (N)'	System	03 Oct 2020 02:51:39

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-02T20:51:23', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2baa3189-34c8-4614-b6f4-056ba517c112'	System	03 Oct 2020 02:51:39
User entered 'No (N)'	System	03 Oct 2020 02:51:39

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-02T20:51:27', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '2baa3189-34c8-4614-b6f4-056ba517c112'	System	03 Oct 2020 02:51:39
User entered '02 Oct 2020 20:51:27'	System	03 Oct 2020 02:51:39

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 71'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-08T00:50:12', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd679cdee-495a-49af-b9b2-ab089f8d7a73'	System	08 Oct 2020 06:50:28
User entered 'No (N)'	System	08 Oct 2020 06:50:28

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-08T00:50:22', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd679cdee-495a-49af-b9b2-ab089f8d7a73'	System	08 Oct 2020 06:50:28
User entered 'No (N)'	System	08 Oct 2020 06:50:28

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-08T00:50:27', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd679cdee-495a-49af-b9b2-ab089f8d7a73' User entered '08 Oct 2020 00:50:27'	System	08 Oct 2020 06:50:28
	System	08 Oct 2020 06:50:28

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 78'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-15T02:29:20', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'dbbd18e0-4839-44cf-a3ca-51c81859243c'	System	15 Oct 2020 08:29:33
User entered 'No (N)'	System	15 Oct 2020 08:29:33

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-15T02:29:25', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'dbbd18e0-4839-44cf-a3ca-51c81859243c'	System	15 Oct 2020 08:29:33
User entered 'No (N)'	System	15 Oct 2020 08:29:33

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-15T02:29:29', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'dbbd18e0-4839-44cf-a3ca-51c81859243c'	System	15 Oct 2020 08:29:33
User entered '15 Oct 2020 02:29:29'	System	15 Oct 2020 08:29:33

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 92'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-29T11:31:53', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8f476a6b-aea7-49cd-87de-db16d2ba0d12'	System	29 Oct 2020 17:32:14
User entered 'No (N)'	System	29 Oct 2020 17:32:14

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-29T11:32:05', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8f476a6b-aea7-49cd-87de-db16d2ba0d12'	System	29 Oct 2020 17:32:14
User entered 'No (N)'	System	29 Oct 2020 17:32:14

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-10-29T11:32:09', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8f476a6b-aea7-49cd-87de-db16d2ba0d12'	System	29 Oct 2020 17:32:14
User entered '29 Oct 2020 11:32:09'	System	29 Oct 2020 17:32:14

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 99'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-06T07:04:30', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '877619a8-8730-425e-a885-fbe00c3b80ed'	System	06 Nov 2020 14:04:38
User entered 'No (N)'	System	06 Nov 2020 14:04:38

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-06T07:04:35', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '877619a8-8730-425e-a885-fbe00c3b80ed'	System	06 Nov 2020 14:04:38
User entered 'No (N)'	System	06 Nov 2020 14:04:38

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-06T07:04:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '877619a8-8730-425e-a885-fbe00c3b80ed' User entered '06 Nov 2020 07:04:38'	System	06 Nov 2020 14:04:38
	System	06 Nov 2020 14:04:38

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 106'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-14T13:01:35', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5292fd67-129a-47b0-8df9-aaa896645e60'	System	14 Nov 2020 20:01:58
User entered 'No (N)'	System	14 Nov 2020 20:01:58

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-14T13:01:49', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5292fd67-129a-47b0-8df9-aaa896645e60'	System	14 Nov 2020 20:01:58
User entered 'No (N)'	System	14 Nov 2020 20:01:58

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-14T13:01:52', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '5292fd67-129a-47b0-8df9-aaa896645e60'	System	14 Nov 2020 20:01:58
User entered '14 Nov 2020 13:01:52'	System	14 Nov 2020 20:01:58

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:27:14
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03
Data entry locked.	System	01 Aug 2020 17:44:36
User entered 'Day 113'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '19 Nov 2020 00:01'	System	01 Aug 2020 17:44:36

US3142043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:22:03
Data entry locked.	System	01 Aug 2020 17:44:36
User entered '23 Nov 2020 23:59'	System	01 Aug 2020 17:44:36

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-19T07:14:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b7c0c1b3-40ef-4b41-8f52-c8f6e7f689d0'	System	19 Nov 2020 14:14:20
User entered 'No (N)'	System	19 Nov 2020 14:14:20

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-19T07:14:14', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b7c0c1b3-40ef-4b41-8f52-c8f6e7f689d0'	System	19 Nov 2020 14:14:20
User entered 'No (N)'	System	19 Nov 2020 14:14:20

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-19T07:14:17', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b7c0c1b3-40ef-4b41-8f52-c8f6e7f689d0'	System	19 Nov 2020 14:14:20
User entered '19 Nov 2020 07:14:17'	System	19 Nov 2020 14:14:20

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-23T07:46:32', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0e0df402-aceb-4173-a182-041513344d6e'	System	23 Nov 2020 14:46:41
User entered 'No (N)'	System	23 Nov 2020 14:46:41

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-23T07:46:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0e0df402-aceb-4173-a182-041513344d6e'	System	23 Nov 2020 14:46:41
User entered 'No (N)'	System	23 Nov 2020 14:46:41

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-23T07:46:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '0e0df402-aceb-4173-a182-041513344d6e'	System	23 Nov 2020 14:46:41
User entered '23 Nov 2020 07:46:39'	System	23 Nov 2020 14:46:41

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-30T10:57:08', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '432faa6c-e33e-46fb-9c29-86fc5016721d'	System	30 Nov 2020 17:57:17
User entered 'No (N)'	System	30 Nov 2020 17:57:17

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-30T10:57:10', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '432faa6c-e33e-46fb-9c29-86fc5016721d'	System	30 Nov 2020 17:57:17
User entered 'No (N)'	System	30 Nov 2020 17:57:17

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-11-30T10:57:13', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '432faa6c-e33e-46fb-9c29-86fc5016721d'	System	30 Nov 2020 17:57:17
User entered '30 Nov 2020 10:57:13'	System	30 Nov 2020 17:57:17

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-07T06:55:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76c33cac-cb84-4acb-bd02-bd34747858b1'	System	07 Dec 2020 13:55:58
User entered 'No (N)'	System	07 Dec 2020 13:55:58

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-07T06:55:46', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76c33cac-cb84-4acb-bd02-bd34747858b1'	System	07 Dec 2020 13:55:58
User entered 'No (N)'	System	07 Dec 2020 13:55:58

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-07T06:55:50', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '76c33cac-cb84-4acb-bd02-bd34747858b1' User entered '07 Dec 2020 06:55:50'	System	07 Dec 2020 13:55:58
	System	07 Dec 2020 13:55:58

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-14T06:06:38', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '232983da-6f8c-43b8-b1bb-fd8270ae0c40'	System	14 Dec 2020 13:06:50
User entered 'No (N)'	System	14 Dec 2020 13:06:50

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-14T06:06:44', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '232983da-6f8c-43b8-b1bb-fd8270ae0c40'	System	14 Dec 2020 13:06:50
User entered 'No (N)'	System	14 Dec 2020 13:06:50

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-14T06:06:46', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '232983da-6f8c-43b8-b1bb-fd8270ae0c40'	System	14 Dec 2020 13:06:50
User entered '14 Dec 2020 06:06:46'	System	14 Dec 2020 13:06:50

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-21T07:23:19', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8b2074b7-1479-4625-8fd4-6dbd618d4da2'	System	21 Dec 2020 14:23:29
User entered 'No (N)'	System	21 Dec 2020 14:23:29

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-21T07:23:21', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8b2074b7-1479-4625-8fd4-6dbd618d4da2'	System	21 Dec 2020 14:23:29
User entered 'No (N)'	System	21 Dec 2020 14:23:29

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-21T07:23:24', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '8b2074b7-1479-4625-8fd4-6dbd618d4da2'	System	21 Dec 2020 14:23:29
User entered '21 Dec 2020 07:23:24'	System	21 Dec 2020 14:23:29

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-28T08:12:59', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '813e0df4-b00e-47c8-8cd3-815890c760e1'	System	28 Dec 2020 15:13:10
User entered 'No (N)'	System	28 Dec 2020 15:13:10

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-28T08:13:02', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '813e0df4-b00e-47c8-8cd3-815890c760e1'	System	28 Dec 2020 15:13:10
User entered 'No (N)'	System	28 Dec 2020 15:13:10

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2020-12-28T08:13:06', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '813e0df4-b00e-47c8-8cd3-815890c760e1' User entered '28 Dec 2020 08:13:06'	System	28 Dec 2020 15:13:10
	System	28 Dec 2020 15:13:10

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-04T06:43:39', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '08c86237-d525-4dff-ba1e-149fa21d4ae7'	System	04 Jan 2021 13:44:07
User entered 'No (N)'	System	04 Jan 2021 13:44:07

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-04T06:43:41', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '08c86237-d525-4dff-ba1e-149fa21d4ae7'	System	04 Jan 2021 13:44:07
User entered 'No (N)'	System	04 Jan 2021 13:44:07

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-04T06:44:05', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '08c86237-d525-4dff-ba1e-149fa21d4ae7'	System	04 Jan 2021 13:44:07
User entered '04 Jan 2021 06:44:05'	System	04 Jan 2021 13:44:07

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-11T05:50:28', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '466a9665-2b35-4e2e-89f1-02e771da8021'	System	11 Jan 2021 12:50:39
User entered 'No (N)'	System	11 Jan 2021 12:50:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-11T05:50:35', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '466a9665-2b35-4e2e-89f1-02e771da8021'	System	11 Jan 2021 12:50:39
User entered 'No (N)'	System	11 Jan 2021 12:50:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-11T05:50:37', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '466a9665-2b35-4e2e-89f1-02e771da8021' User entered '11 Jan 2021 05:50:37'	System	11 Jan 2021 12:50:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-18T09:42:51', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b84f2898-398b-4f87-bd4c-24af6ae0222a'	System	18 Jan 2021 16:42:59
User entered 'No (N)'	System	18 Jan 2021 16:42:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-18T09:42:53', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b84f2898-398b-4f87-bd4c-24af6ae0222a'	System	18 Jan 2021 16:42:59
User entered 'No (N)'	System	18 Jan 2021 16:42:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-18T09:42:55', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b84f2898-398b-4f87-bd4c-24af6ae0222a'	System	18 Jan 2021 16:42:59
User entered '18 Jan 2021 09:42:55'	System	18 Jan 2021 16:42:59

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-27T20:03:06', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c5f90ed4-d744-44de-9ef0-bcb90347a513'	System	28 Jan 2021 03:03:18
User entered 'No (N)'	System	28 Jan 2021 03:03:18

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-27T20:03:09', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c5f90ed4-d744-44de-9ef0-bcb90347a513'	System	28 Jan 2021 03:03:18
User entered 'No (N)'	System	28 Jan 2021 03:03:18

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-01-27T20:03:12', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c5f90ed4-d744-44de-9ef0-bcb90347a513'	System	28 Jan 2021 03:03:18
User entered '27 Jan 2021 20:03:12'	System	28 Jan 2021 03:03:18

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-01T07:54:15', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a6403766-6677-4a87-9b53-ac1313ce6f8f'	System	01 Feb 2021 14:54:36
User entered 'No (N)'	System	01 Feb 2021 14:54:36

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-01T07:54:17', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a6403766-6677-4a87-9b53-ac1313ce6f8f'	System	01 Feb 2021 14:54:36
User entered 'No (N)'	System	01 Feb 2021 14:54:36

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-01T07:54:20', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'a6403766-6677-4a87-9b53-ac1313ce6f8f'	System	01 Feb 2021 14:54:36
User entered '01 Feb 2021 07:54:20'	System	01 Feb 2021 14:54:36

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-08T06:27:28', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd64851a7-128c-4e56-8524-92e7a746e109'	System	08 Feb 2021 13:27:38
User entered 'No (N)'	System	08 Feb 2021 13:27:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-08T06:27:31', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd64851a7-128c-4e56-8524-92e7a746e109'	System	08 Feb 2021 13:27:38
User entered 'No (N)'	System	08 Feb 2021 13:27:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-08T06:27:34', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd64851a7-128c-4e56-8524-92e7a746e109'	System	08 Feb 2021 13:27:38
User entered '08 Feb 2021 06:27:34'	System	08 Feb 2021 13:27:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-15T06:34:26', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b6e87c8a-acd2-4810-99ac-9d82c8e33f2f'	System	15 Feb 2021 13:34:37
User entered 'No (N)'	System	15 Feb 2021 13:34:37

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-15T06:34:29', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b6e87c8a-acd2-4810-99ac-9d82c8e33f2f'	System	15 Feb 2021 13:34:37
User entered 'No (N)'	System	15 Feb 2021 13:34:37

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-02-15T06:34:31', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'b6e87c8a-acd2-4810-99ac-9d82c8e33f2f' User entered '15 Feb 2021 06:34:31'	System	15 Feb 2021 13:34:37
	System	15 Feb 2021 13:34:37

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-01T06:03:55-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '9e176226-9c3b-403e-bd49-35c412dbb237'	System	01 Mar 2021 13:04:09
User entered 'No (N)'	System	01 Mar 2021 13:04:09

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-01T06:04:00-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '9e176226-9c3b-403e-bd49-35c412dbb237'	System	01 Mar 2021 13:04:09
User entered 'No (N)'	System	01 Mar 2021 13:04:09

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-01T06:04:03-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '9e176226-9c3b-403e-bd49-35c412dbb237'	System	01 Mar 2021 13:04:09
User entered '01 Mar 2021 06:04:03'	System	01 Mar 2021 13:04:09

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-08T06:10:15-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'bcc9f158-1095-42a2-81bb-368109528466'	System	08 Mar 2021 13:10:25
User entered 'No (N)'	System	08 Mar 2021 13:10:25

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-08T06:10:18-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'bcc9f158-1095-42a2-81bb-368109528466'	System	08 Mar 2021 13:10:25
User entered 'No (N)'	System	08 Mar 2021 13:10:25

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-08T06:10:21-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'bcc9f158-1095-42a2-81bb-368109528466'	System	08 Mar 2021 13:10:25
User entered '08 Mar 2021 06:10:21'	System	08 Mar 2021 13:10:25

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-15T08:27:19-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '6c63b8de-e6e4-48b7-9da8-fc2871b6a09d'	System	15 Mar 2021 14:27:26
User entered 'No (N)'	System	15 Mar 2021 14:27:26

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-15T08:27:21-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '6c63b8de-e6e4-48b7-9da8-fc2871b6a09d'	System	15 Mar 2021 14:27:26
User entered 'No (N)'	System	15 Mar 2021 14:27:26

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-15T08:27:24-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '6c63b8de-e6e4-48b7-9da8-fc2871b6a09d' User entered '15 Mar 2021 08:27:24'	System	15 Mar 2021 14:27:26
	System	15 Mar 2021 14:27:26

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-22T07:29:04-05:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '4b22a541-1e95-48db-bdca-b6c240c5d6d9'	System	22 Mar 2021 12:29:08
User entered 'No (N)'	System	22 Mar 2021 12:29:08

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-22T07:29:07-05:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '4b22a541-1e95-48db-bdca-b6c240c5d6d9'	System	22 Mar 2021 12:29:08
User entered 'No (N)'	System	22 Mar 2021 12:29:08

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-22T07:29:10-05:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '4b22a541-1e95-48db-bdca-b6c240c5d6d9'	System	22 Mar 2021 12:29:08
User entered '22 Mar 2021 07:29:10'	System	22 Mar 2021 12:29:08

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-05T16:13:29-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1d0d4eb8-3dbf-4f97-ab16-f37bcef10787'	System	05 Apr 2021 22:13:38
User entered 'No (N)'	System	05 Apr 2021 22:13:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-05T16:13:31-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1d0d4eb8-3dbf-4f97-ab16-f37bcef10787'	System	05 Apr 2021 22:13:38
User entered 'No (N)'	System	05 Apr 2021 22:13:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-05T16:13:34-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1d0d4eb8-3dbf-4f97-ab16-f37bcef10787' User entered '05 Apr 2021 16:13:34'	System	05 Apr 2021 22:13:38
	System	05 Apr 2021 22:13:38

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-12T07:03:23-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c49f308f-c774-434d-9bea-b3e5a4aa8d68'	System	12 Apr 2021 13:03:34
User entered 'No (N)'	System	12 Apr 2021 13:03:34

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-12T07:03:26-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c49f308f-c774-434d-9bea-b3e5a4aa8d68'	System	12 Apr 2021 13:03:34
User entered 'No (N)'	System	12 Apr 2021 13:03:34

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-12T07:03:32-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'c49f308f-c774-434d-9bea-b3e5a4aa8d68'	System	12 Apr 2021 13:03:34
User entered '12 Apr 2021 07:03:32'	System	12 Apr 2021 13:03:34

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-19T07:27:43-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '44f74572-e6ed-418e-8330-ff63de3d8033'	System	19 Apr 2021 13:27:54
User entered 'No (N)'	System	19 Apr 2021 13:27:54

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-19T07:27:48-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '44f74572-e6ed-418e-8330-ff63de3d8033'	System	19 Apr 2021 13:27:54
User entered 'No (N)'	System	19 Apr 2021 13:27:54

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-19T07:27:51-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '44f74572-e6ed-418e-8330-ff63de3d8033'	System	19 Apr 2021 13:27:54
User entered '19 Apr 2021 07:27:51'	System	19 Apr 2021 13:27:54

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-26T06:03:33-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '66d97570-56a4-4d63-a299-55e7276f48bb'	System	26 Apr 2021 12:03:39
User entered 'No (N)'	System	26 Apr 2021 12:03:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-26T06:03:36-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '66d97570-56a4-4d63-a299-55e7276f48bb'	System	26 Apr 2021 12:03:39
User entered 'No (N)'	System	26 Apr 2021 12:03:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-04-26T06:03:39-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '66d97570-56a4-4d63-a299-55e7276f48bb'	System	26 Apr 2021 12:03:39
User entered '26 Apr 2021 06:03:39'	System	26 Apr 2021 12:03:39

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-05-03T06:28:40-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1f06dd18-1e0e-4c9a-abbe-8bb799180e18'	System	03 May 2021 12:29:06
User entered 'No (N)'	System	03 May 2021 12:29:06

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-05-03T06:28:44-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1f06dd18-1e0e-4c9a-abbe-8bb799180e18'	System	03 May 2021 12:29:06
User entered 'Yes (Y)'	System	03 May 2021 12:29:06

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-05-03T06:28:53-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1f06dd18-1e0e-4c9a-abbe-8bb799180e18'	System	03 May 2021 12:29:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 12:29:06

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-05-03T06:28:56-06:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: '1f06dd18-1e0e-4c9a-abbe-8bb799180e18'	System	03 May 2021 12:29:06
User entered '03 May 2021 06:28:56'	System	03 May 2021 12:29:06

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:22:03

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:22:03

US3142043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:22:03
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:22:03

US3142043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:00:33

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-01T06:04:12-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd7463ffa-4423-4c0c-8ea8-05f631fe5b1b'	System	01 Mar 2021 13:04:18
User entered 'No (N)'	System	01 Mar 2021 13:04:18

US3142043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:00:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:59:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b3792c3901180195)', Time: '2021-03-01T06:04:15-07:00', User OID: 'PatientReportedOutcome (US3142043)', ODM File OID: 'd7463ffa-4423-4c0c-8ea8-05f631fe5b1b'	System	01 Mar 2021 13:04:18
User entered '01 Mar 2021 06:04:15'	System	01 Mar 2021 13:04:18

US3142043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	27 Oct 2020 19:09:21

US3142043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '26 Oct 2020'	Dalia Jeronimo (b) (4)	27 Oct 2020 19:09:21

US3142043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	27 Oct 2020 19:09:21

US3142043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Dalia Jeronimo (b) (4)	27 Oct 2020 19:09:21

US3142043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	27 Oct 2020 19:09:26

US3142043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:56:52
User entered 'I'	System	27 Oct 2020 19:09:26

US3142043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Mar 2021 21:37:06

US3142043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 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)	02 Mar 2021 08:24:02
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	01 Mar 2021 21:38:29
User entered '01 Dec 2020' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	01 Mar 2021 21:38:29
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Stated as documented.' (Site from System).	Lisa Jackson (b) (4) (b) (4)	01 Mar 2021 21:38:09
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	01 Mar 2021 21:37:06
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Mar 2021 21:37:06
User entered '01 Dec 2021'	Lisa Jackson (b) (4) (b) (4)	01 Mar 2021 21:37:06

US3142043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4)	01 Mar 2021 21:37:06

US3142043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	01 Mar 2021 21:37:06

US3142043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	08 Jan 2021 18:13:07

US3142043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User entered '1'	System	08 Jan 2021 18:13:07

US3142043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	08 Jan 2021 18:13:18

US3142043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:56:35
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	21 Jan 2021 16:54:00
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Jan 2021 18:13:18
User entered '8 Jan 2021'	Jami Wagner (b) (4) (b) (4)	08 Jan 2021 18:13:18

US3142043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	08 Jan 2021 18:13:18

US3142043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	08 Jan 2021 18:13:18

US3142043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	08 Jan 2021 18:13:25

US3142043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User entered 'I'	System	08 Jan 2021 18:13:25

US3142043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:22:57
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:07:56

US3142043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:22:58
User entered '28 Jan 2021'	Jami Wagner (b) (4)	01 Feb 2021 22:07:56

US3142043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:23:00
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	01 Feb 2021 22:07:56

US3142043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:23:01
User closed query 'Per DM CLR: Comment = PT STARTED TAKING HYDROCHLOROTHAZIDE ONCE A DAY FOR HB 25MG. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).		03 Mar 2021 13:40:40
Query 'Per DM CLR: Comment = PT STARTED TAKING HYDROCHLOROTHAZIDE ONCE A DAY FOR HB 25MG. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' answered with 'now added to conmed page ' (Site from DM).	Jill York (b) (4)	01 Mar 2021 18:08:59
User opened query 'Per DM CLR: Comment = PT STARTED TAKING HYDROCHLOROTHAZIDE ONCE A DAY FOR HB 25MG. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 22:42:37
User entered 'pt started taking hydrochlorothazide once a day for hb 25mg'	Jami Wagner (b) (4) (b) (4)	01 Feb 2021 22:07:56

US3142043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:32:21
User entered 'Yes (Y)'	Jami Wagner (b) (4)	01 Feb 2021 22:08:02

US3142043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:05:04
User entered '1'	System	01 Feb 2021 22:08:02

US3142043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	30 Mar 2021 19:56:25

US3142043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '09 Mar 2021'	Lisa Jackson (b) (4)	30 Mar 2021 19:56:25

US3142043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4)	30 Mar 2021 19:56:25

US3142043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered 'VISIT4'	System	30 Mar 2021 19:56:25

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'No (N)'	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered empty.	System	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered empty.	System	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered empty.	System	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered empty.	System	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered empty.	System	30 Mar 2021 19:56:38

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55

US3142043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55

US3142043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'No (N)'	Lisa Jackson (b) (4)	30 Mar 2021 19:56:45

US3142043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered empty.	Lisa Jackson (b) (4)	30 Mar 2021 19:56:45

US3142043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	30 Mar 2021 19:57:29

US3142043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '09 Mar 2021'	Lisa Jackson (b) (4)	30 Mar 2021 19:57:29

US3142043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered '13:24'	Lisa Jackson (b) (4)	30 Mar 2021 19:57:29

US3142043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered '09 Mar 2021 13:24'	System	30 Mar 2021 19:57:29

US3142043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:47
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	30 Mar 2021 19:57:36

US3142043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:04:55
User entered 'I'	System	30 Mar 2021 19:57:36

US3142043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	15 Apr 2021 21:58:47
	(b) (4)	

US3142043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 18:40:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'outside window. data is correct as documented' (Site from System).	Lisa Jackson (b) (4)	15 Apr 2021 22:00:51
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Apr 2021 21:58:47
User entered '14 Apr 2021'	Lisa Jackson (b) (4)	15 Apr 2021 21:58:47

US3142043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 21:58:47

US3142043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) Lisa Jackson (b) (4)	15 Apr 2021 21:58:47
	(b) (4)	

US3142043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	15 Apr 2021 22:01:11
	(b) (4)	

US3142043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 22:01:11

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:33

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:14:28
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:02:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:33

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:14:28
User entered '13:00'	Shelby Pickle (b) (4)	03 Dec 2020 17:02:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:33

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:58
User entered '02 Dec 2020 13:00'	System	03 Dec 2020 17:02:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:33

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:14:28
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Shelby Pickle (b) (4)	03 Dec 2020 17:02:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:33

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:58:58
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:14:28
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:02:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 1 (Day 1)'	(b) (4) Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '30 Nov 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 2 (Day 2)'	(b) (4) Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '01 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 17:04:55

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 3 (Day 3)'	(b) (4) Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '90'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '98.2' F	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 17:16:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 4 (Day 4)'	(b) (4) Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '03 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '91'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '97.9' F	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	03 Dec 2020 22:29:46

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 5 (Day 5)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '04 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '92'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '97.8' F	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:42

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Shelby Pickle (b) (4)	21 Jan 2021 22:24:10
User entered 'Day 5 (Day 5)'	(b) (4)	
	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58
	(b) (4)	

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '05 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'l'	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered empty.	System	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:23:58

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 7 (Day 7)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '06 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '90'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '97.9' F	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:25:12

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:25:12

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 8 (Day 8)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '07 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '90'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '98.3' F	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:26:15

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 9 (Day 9)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '08 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '89'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '98.6' F	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Moderate (Moderate)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:27:13

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 10 (Day 10)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '09 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'l'	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered empty.	System	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:45:47

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 11 (Day 11)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '10 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'l'	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered empty.	System	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:46:02

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 12 (Day 12)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '11 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '92'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '98.0' F	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'Mild (Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:51:30

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 13 (Day 13)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '12 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '91'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '97.4' F	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:33

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 14 (Day 14)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '13 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'l'	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered empty.	System	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:52:47

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 15 (Day 15)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '14 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'l'	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered empty.	System	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:53:00

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Day 16 (Day 16)'	(b) (4) Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '15 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '92'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User entered '%'	System	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered '97.9' F	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:00:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:46:37
User entered 'None (None)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:26

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:17
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[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 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:19
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

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 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:13:21
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).		28 Dec 2020 16:48:05
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 'Subject tested possitive ' (Site from System).	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:13:32
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 18:13:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 18:13:08
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	18 Dec 2020 18:13:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:13:08
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:17:01
User entered empty.	Shelby Pickle (b) (4) (b) (4)	03 Dec 2020 17:17:01

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:27
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:13:29
User entered 'Nasopharyngeal Swab (NasopharyngealSwab)'	Shelby Pickle (b) (4) (b) (4)	03 Dec 2020 17:17:01

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:30
User entered empty.	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[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 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:33
User entered 'No (N)'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:52
User entered empty.	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:13:54
User entered empty.	Shelby Pickle (b) (4)	03 Dec 2020 17:17:01

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Folder: Covid-19 Assessment 02 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:00:33

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:35
User entered 'I'	System	18 Dec 2020 18:13:08

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:34
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:36
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

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 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered '15 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered '90'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 22:56:14

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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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 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
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Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:00:33

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:05:42
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 22:56:14

US3142043

Folder: Covid-19 Assessment 02 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:00:33

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:07:41
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 22:54:44

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:54:33
DataPoint Un-verified.		21 Apr 2021 00:55:18
DataPoint Verified.		21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:21:09
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:54:33
DataPoint Un-verified.		21 Apr 2021 00:55:20
DataPoint Verified.		21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:21:09
	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:21:45
User entered 'No (N)'	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:08:30
User entered '06 Dec 2020' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:21:45
User entered empty.	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:22:27
User entered 'No (N)'	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:08:30
User entered '09 Dec 2020' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:22:27
User entered empty.	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:22:58
User entered 'No (N)'	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:08:30
User entered '11 Dec 2020' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:22:58
User entered empty.	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:23:34
User entered 'No (N)'	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:23:34
User entered empty.	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:24:12
User entered 'No (N)'	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:24:12
User entered empty.	(b) (4)	
	Jami Wagner (b) (4)	05 Apr 2021 20:46:12
	(b) (4)	

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jami Wagner (b) (4) (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Jami Wagner (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:54:59
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	05 Apr 2021 20:46:12

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:02:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Lisa Jackson (b) (4)	15 Apr 2021 16:34:06

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User closed query 'Per ETRTR, Please complete Saliva Collection Page. Thanks!' (Site from CRA). DataPoint Verified.	(b) (4)	21 Apr 2021 22:02:06
	(b) (4)	21 Apr 2021 18:49:27
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
Query 'Per ETRTR, Please complete Saliva Collection Page. Thanks!' answered with 'SALIVA COLLECTION PAGE IS COMPLETED' (Site from CRA).	Lisa Jackson (b) (4)	15 Apr 2021 16:25:06
	(b) (4)	
Query 'Please enter all illness visits into EDC' canceled (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 18:18:52
User opened query 'Please enter all illness visits into EDC' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 16:59:53
User opened query 'Per ETRTR, Please complete Saliva Collection Page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 17:23:03
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:31
	(b) (4)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:19
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:31

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[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 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:08:24
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	03 Dec 2020 17:17:31

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'SICKD1'	System	03 Dec 2020 17:17:31

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '13:01'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered '02 Dec 2020 13:01'	System	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34
DataPoint set to visible.	System	03 Dec 2020 17:17:31

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered missing code ND - Not Done.	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34
DataPoint set to visible.	(b) (4) System	03 Dec 2020 17:17:31

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '98.2' F	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered 'Other (Other)'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered 'Temporal'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '80'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'bpm'	System	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '13'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'breaths/min'	System	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '130'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'mmHg'	System	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:09:34
User entered '92'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'mmHg'	System	03 Dec 2020 17:19:34

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:10:13
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:43

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:10:13
User entered '02 Dec 2020'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:43

US3142043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[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 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:10:35
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	03 Dec 2020 17:19:59

US3142043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:10:35
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As per the previous query response if tracking number cannot be provided, however please provide Accession number for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).		09 Feb 2021 08:27:21
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As per the previous query response if tracking number cannot be provided, however please provide Accession number for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Tracking and accession number cannot be provided/' (Site from DM).	Jill York (b) (4)	03 Feb 2021 17:15:28
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As per the previous query response if tracking number cannot be provided, however please provide Accession number for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:25:02
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).		02 Feb 2021 05:25:02

US3142043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Tracking number can not be provided. ' (Site from DM).	Meghan York (b) (4)	25 Jan 2021 17:04:26
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 DEC 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:24:06
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 06:53:24
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample has been shipped, however, tracking number cannot be provided ' (Site from DM).	Meghan York (b) (4)	22 Dec 2020 16:39:58

US3142043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '02 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 11:30:41
	Shelby Pickle (b) (4) (b) (4)	03 Dec 2020 17:19:59

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User closed query 'Per GCL LAB reconciliation: Saliva: Please note that Illness Visit 1 and Illness Visit 2 are reported with the same date. Hence please remove the data for the duplicate entry.' (Site from DM).		23 Apr 2021 09:48:25
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:55:02
Query 'Per GCL LAB reconciliation: Saliva: Please note that Illness Visit 1 and Illness Visit 2 are reported with the same date. Hence please remove the data for the duplicate entry.' answered with 'data now corrected ' (Site from DM).	Jill York (b) (4)	21 Apr 2021 14:58:21
User opened query 'Per GCL LAB reconciliation: Saliva: Please note that Illness Visit 1 and Illness Visit 2 are reported with the same date. Hence please remove the data for the duplicate entry.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:47:56
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:55:02
Signature has been broken.	Jill York (b) (4)	21 Apr 2021 14:57:09
User entered '02 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 14:57:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '07 Jan 2021'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[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 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:02
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Clinic (Clinic)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'SICKD1'	System	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:55:09
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Apr 2021 14:57:26
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Apr 2021 14:57:26
Signature has been broken.	Jill York (b) (4)	21 Apr 2021 14:57:26
User entered '02 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 14:57:26
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Apr 2021 14:57:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '07 Jan 2021'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10:44'	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered '02 Dec 2020 10:44'	System	21 Apr 2021 14:57:26
User entered '07 Jan 2021 10:44'	System	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	
DataPoint set to visible.	System	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	
DataPoint set to visible.	System	15 Apr 2021 16:30:12

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '98.4' F	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'TEMPORAL'	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '90'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'bpm'	System	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10'	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:31:39
	(b) (4)	

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'breaths/min'	System	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '136'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'mmHg'	System	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User entered 'mmHg'	System	15 Apr 2021 16:31:39

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04

US3142043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
DataPoint Verified.		22 Apr 2021 16:55:43
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:32:25

US3142043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:55:43
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Apr 2021 14:57:39
Signature has been broken.	Jill York (b) (4)	21 Apr 2021 14:57:39
User entered '02 Dec 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 14:57:39
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Apr 2021 14:57:09
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '07 Jan 2021'	(b) (4) Lisa Jackson (b) (4) (b) (4)	15 Apr 2021 16:32:25

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:53:15
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	18 Jan 2021 16:51:09

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:53:15
User closed query 'Per GCL LAB reconciliation: Saliva: Re-query: Thanks for your response, however please review the preclarus data sample has been reported for this subject as collection date 07JAN2021, if samples were collected for this subject then please update actual sample collection date in EDC and preclarus data via DCF. ' (Site from DM).		20 Apr 2021 07:07:17
Query 'Per GCL LAB reconciliation: Saliva: Re-query: Thanks for your response, however please review the preclarus data sample has been reported for this subject as collection date 07JAN2021, if samples were collected for this subject then please update actual sample collection date in EDC and preclarus data via DCF. ' answered with 'saliva collection folder is populated with the dates of collection' (Site from DM).	Jill York (b) (4)	19 Apr 2021 16:54:58
User opened query 'Per GCL LAB reconciliation: Saliva: Re-query: Thanks for your response, however please review the preclarus data sample has been reported for this subject as collection date 07JAN2021, if samples were collected for this subject then please update actual sample collection date in EDC and preclarus data via DCF. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:20:05
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' (Site from DM).		16 Apr 2021 05:20:05

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' answered with 'Illness Visit (2) has been entered from Source. No Saliva Samples were collected on 07JAN2021' (Site from DM).	Lisa Jackson (b) (4)	15 Apr 2021 16:38:05
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07JAN2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an illness visit and record the data on the Saliva collection form. Thank you' (Site from DM). User entered '07 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 16:46:41
	Shelby Pickle (b) (4)	18 Jan 2021 16:51:09

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[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 19:23:19
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:53:15
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	18 Jan 2021 16:51:09

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'SICKD28'	System	18 Jan 2021 16:51:09

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4)	
	Shelby Pickle (b) (4)	18 Jan 2021 16:51:51
	(b) (4)	

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '07 Jan 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10:44'	(b) (4)	
	Shelby Pickle (b) (4)	18 Jan 2021 16:51:51
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered '07 Jan 2021 10:44'	System	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '98.4' F	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '90'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'bpm'	System	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'breaths/min'	System	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '136'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'mmHg'	System	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:29
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'mmHg'	System	18 Jan 2021 16:51:51

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4)	
	Shelby Pickle (b) (4)	18 Jan 2021 16:52:02
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:53:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '07 Jan 2021'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:52:02

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[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 19:23:19
DataPoint Verified.		22 Apr 2021 16:54:01
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:52:12

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:00:33

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per Lab Recon: SARS-COV2: Sample dated 07 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you. ' answered with 'Sample has been shipped, however, accession and tracking number cannot be provided ' (Site from DM).	Jill York (b) (4)	03 Feb 2021 17:14:58
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 07 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4), (b) (6)	28 Jan 2021 12:32:13
' (Site from DM). User entered '07 Jan 2021'	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:52:12

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:56:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:34:25
	(b) (4)	

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
DataPoint Verified.		22 Apr 2021 16:56:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:34:25
	(b) (4)	

US3142043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[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 19:23:19
DataPoint Verified.		22 Apr 2021 16:56:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:34:25
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:19
User entered 'SICKD28'	System	15 Apr 2021 16:34:25

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 19:19:52

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 20:53:36
User entered '7 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 19:19:52
	(b) (4)	

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4)	15 Jan 2021 19:19:52

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 19:19:52

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
Signature has been broken.	Jill York (b) (4)	23 Apr 2021 15:44:28
User entered '7 Jan 2021' reason for change: Data Entry Error	Jill York (b) (4)	23 Apr 2021 15:44:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 20:55:42
User entered '7 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 19:21:01

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:55:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:06:26

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 19:21:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:55:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:06:26

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User closed query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' (Site from DM). User signature succeeded.	(b) (4)	29 Apr 2021 03:06:13
Query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' answered with 'updated' (Site from DM). Signature has been broken.	Ripley Hollister (b) (4)	26 Apr 2021 02:38:44
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 7Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' (Site from DM). User closed query 'PER CDM: Please confirm if 09Mar2021 date is confirmed on source. If so, kindly review date in IRT and update as necessary. ' (Site from DM). User signature succeeded.	Jill York (b) (4)	23 Apr 2021 15:44:46
Query 'PER CDM: Please confirm if 09Mar2021 date is confirmed on source. If so, kindly review date in IRT and update as necessary. ' answered with 'Subject was unblinded 07JAN2021. Unable to be vaccinated due to ILLNESS VISIT 2. Did 2nd UNBLINDING on 09MAR2021. Source reflects situation. ' (Site from DM).	Jill York (b) (4)	23 Apr 2021 15:44:28
	Jill York (b) (4)	23 Apr 2021 15:44:28
	(b) (4), (b) (6)	23 Apr 2021 12:42:05
	(b) (4)	19 Apr 2021 14:07:50
	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
	Lisa Jackson (b) (4)	15 Apr 2021 16:42:10
	(b) (4)	

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EAB) (1725)

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

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Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PER CDM: Please confirm if 09Mar2021 date is confirmed on source. If so, kindly review date in IRT and update as necessary. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:44:47
User closed query 'Per IRT, subject was unblinded on 07JAN2021. Please review and reconcile.' (Site from DM).		15 Apr 2021 14:39:14
Query 'Per IRT, subject was unblinded on 07JAN2021. Please review and reconcile.' answered with 'Source is accurate. 07JAN2021 is for COVID Confirmation.' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 18:02:23
User entered '09 Mar 2021' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 17:55:14
User opened query 'Per IRT, subject was unblinded on 07JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:52:59
User entered '9 Mar 2021' reason for change: Data Entry Error		09 Mar 2021 20:55:42
User entered '7 Jan 2021'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 19:21:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
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 20:18:45
Query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'Subject started study as a Placebo.' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 18:02:42
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	08 Apr 2021 17:54:23
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 16:00:51
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error		09 Mar 2021 20:55:42
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	18 Jan 2021 16:50:32
User entered 'mRNA-1273 (mRNA-1273)'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 19:21:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 05:56:25
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	System	20 Jan 2021 05:56:25
User entered 'mRNA-1273 (mRNA-1273)'	Shelby Pickle (b) (4)	18 Jan 2021 16:50:32
	(b) (4)	
	Jami Wagner (b) (4)	15 Jan 2021 19:21:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 05:56:25
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	System	20 Jan 2021 05:56:25
User entered 'mRNA-1273 (mRNA-1273)'	Shelby Pickle (b) (4)	18 Jan 2021 16:50:32
	(b) (4)	
	Jami Wagner (b) (4)	15 Jan 2021 19:21:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Shelby Pickle (b) (4)	18 Jan 2021 16:50:32
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	15 Jan 2021 19:21:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

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[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '1'	System	18 Jan 2021 16:50:32
User entered empty.	System	15 Jan 2021 19:21:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:00:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'I'	System	18 Jan 2021 16:50:32
User entered empty.	System	15 Jan 2021 19:21:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

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[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered empty.	System	09 Mar 2021 21:00:45
DataPoint set to visible.	System	18 Jan 2021 16:50:32

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered empty.	System	09 Mar 2021 21:00:45
DataPoint set to visible.	System	18 Jan 2021 16:50:32

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User accepted default value 'Pre-Dose (PREDOSE)'		09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '13:12'	(b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '9 Mar 2021 13:12'	System	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '91'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'bpm'	System	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'breaths/min'	System	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '112'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'mmHg'	System	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '79'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'mmHg'	System	09 Mar 2021 21:00:45

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:00:45

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered empty.	System	09 Mar 2021 21:00:45
DataPoint set to visible.	System	18 Jan 2021 16:50:32

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User accepted default value 'Post-Dose (POSTDOSE)'		09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '14:01'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '9 Mar 2021 14:01'	System	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '86'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'bpm'	System	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'breaths/min'	System	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '128'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'mmHg'	System	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '89'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'mmHg'	System	09 Mar 2021 21:07:49

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:01

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:01

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'mRNA-1273'	System	09 Mar 2021 20:56:39
DataPoint set to visible.	System	18 Jan 2021 16:50:32

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '13:31'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '9 Mar 2021 13:31'	System	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'ONCE'	System	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 20:56:39

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:29:01
User closed query 'Per GCL LAB Recon: Requery: Immunogenicity: Per response, Illness D28 visit does not have Immuno sample collected but a Blood sample for SARS-COV2 evaluation is collected. Please confirm if Barcode# 1F636152551 collected on 07Jan2021 is for SARS-COV2 sample type for Illness D28 visit then please inform Preclarus to update sample type as it reflected as Immuno sample or if 07Jan2021 sample was collected as Immuno sample along with SARS-COV2 sample then please update as an additional sample under UNSCHEDULED visit on Immunogenicity Assessment form.' (Site from DM).		29 Apr 2021 07:31:21
Query 'Per GCL LAB Recon: Requery: Immunogenicity: Per response, Illness D28 visit does not have Immuno sample collected but a Blood sample for SARS-COV2 evaluation is collected. Please confirm if Barcode# 1F636152551 collected on 07Jan2021 is for SARS-COV2 sample type for Illness D28 visit then please inform Preclarus to update sample type as it reflected as Immuno sample or if 07Jan2021 sample was collected as Immuno sample along with SARS-COV2 sample then please update as an additional sample under UNSCHEDULED visit on Immunogenicity Assessment form.' answered with '07Jan2021 was a D28 convalescence visit' (Site from DM).	Jill York (b) (4)	19 Apr 2021 17:11:04
User opened query 'Per GCL LAB Recon: Requery: Immunogenicity: Per response, Illness D28 visit does not have Immuno sample collected but a Blood sample for SARS-COV2 evaluation is collected. Please confirm if Barcode# 1F636152551 collected on 07Jan2021 is for SARS-COV2 sample type for Illness D28 visit then please inform Preclarus to update sample type as it reflected as Immuno sample or if 07Jan2021 sample was collected as Immuno sample along with SARS-COV2 sample then please update as an additional sample under UNSCHEDULED visit on Immunogenicity Assessment form.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 12:28:36

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EAB) (1725)

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has two sample, 07Jan21 Barcode: 1F636152551 labelled as OL-D1 which is missing in EDC and 09MAR2021 Barcode: 1F636482585 labelled as UNSCHEDULED visit which matches the OL-D1 visit sample. Please review both the Barcode in Preclarus and confirm the correct visit label for 09Mar21 sample. Also review if 07Jan21 sample was collected for the subject then record under UNSCHEDULED visit as an additional sample or confirm the correct subject to which this sample belongs.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 12:28:36
	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Query 'Per GCL LAB Recon: Immunogenicity: GCL has two sample, 07Jan21 Barcode: 1F636152551 labelled as OL-D1 which is missing in EDC and 09MAR2021 Barcode: 1F636482585 labelled as UNSCHEDULED visit which matches the OL-D1 visit sample. Please review both the Barcode in Preclarus and confirm the correct visit label for 09Mar21 sample. Also review if 07Jan21 sample was collected for the subject then record under UNSCHEDULED visit as an additional sample or confirm the correct subject to which this sample belongs.' answered with '07JAN2021 was drawn for ILLNESS D28, 1F636152551. Patient was unblinded during visit but did not receive vaccination on that day. 09MAR2021 Is the actual vaccination visit that was connected to D209 V4 MONTH7, 1F636482585.	Lisa Jackson (b) (4)	15 Apr 2021 16:12:45
' (Site from DM).		

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:29:01
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as per preclarus report, in PPD GCL, it is recorded as collected on "07 JAN 2021", however here in EDC, it is recorded as collected on "09 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 01:49:07
' (Site from DM). Query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as per preclarus report, in PPD GCL, it is recorded as collected on "07 JAN 2021", however here in EDC, it is recorded as collected on "09 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you.	Jill York (b) (4)	23 Mar 2021 16:54:48
' answered with '9 MAR 2021 is the correct date ' (Site from DM). User opened query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this sample, as per preclarus report, in PPD GCL, it is recorded as collected on "07 JAN 2021", however here in EDC, it is recorded as collected on "09 MAR 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you.	(b) (4), (b) (6)	22 Mar 2021 08:50:28
' (Site from DM). User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	09 Mar 2021 20:58:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is prior to the System Participant Decision Visit Date. Please review and reconcile.' (Site from System).		09 Mar 2021 20:58:41
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 20:58:41
User opened query 'The Collection Date is before the System Date of Updated Informed Consent. Please review and reconcile.' (Site from System).		09 Mar 2021 20:55:42
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 20:53:36
User entered '7 Jan 2021'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 19:21:36

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:29:01
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '13:24' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:58:41
User entered '11:03'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 19:21:36

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:29:01
User entered '9 Mar 2021 13:24'	System	09 Mar 2021 20:58:41
User entered '7 Jan 2021 11:03'	System	15 Jan 2021 19:21:36

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 19:21:54

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "07-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:46:39
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "07-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' answered with 'data entered in EDC is correct ' (Site from DM).	Jill York (b) (4)	23 Mar 2021 16:54:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-MAR-2021" is recorded under Participant Decision Visit / OL-D1 visit in EDC; however, in PPD portal, it is recorded as "07-JAN-2021" for OL-1 visit. Kindly review the collection date and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:35:21
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	09 Mar 2021 20:58:56
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 20:58:56
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	09 Mar 2021 20:55:42
User entered '7 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 19:21:54

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '13:25' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 20:59:20
User entered '11:00'	Jami Wagner (b) (4)	15 Jan 2021 19:21:54

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:33

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '9 Mar 2021 13:25'	System	09 Mar 2021 20:59:20
User entered '9 Mar 2021 11:00'	System	09 Mar 2021 20:58:56
User entered '7 Jan 2021 11:00'	System	15 Jan 2021 19:21:54

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	18 Jan 2021 16:50:38

US3142043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:31
User entered '1'	System	18 Jan 2021 16:50:38

US3142043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:13:59

US3142043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
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). 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 entered as correct' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:34:21 23 Mar 2021 20:14:55
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 20:13:59
User entered '23 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 20:13:59

US3142043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:13:59

US3142043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:13:59

US3142043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:15:48

US3142043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User entered 'I'	System	23 Mar 2021 20:15:48

US3142043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:36:07
User entered 'I'	System	23 Mar 2021 20:15:48
DataPoint set to visible.	System	23 Mar 2021 20:15:48

US3142043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Apr 2021 15:38:44
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:31:46
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'DATA IS AS DOCUMENTED' (Site from System).	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:39:08
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 15:38:44
User entered '01 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:38:44

US3142043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4)	01 Apr 2021 15:38:44
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 15:38:44

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '01 Apr 2021'	Lisa Jackson (b) (4)	01 Apr 2021 15:40:51
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '08:53'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 08:53'	System	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '97.5' F	Lisa Jackson (b) (4)	01 Apr 2021 15:40:51
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Other (Other)'	Lisa Jackson (b) (4)	01 Apr 2021 15:40:51
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'TEMPORAL83'	Lisa Jackson (b) (4)	01 Apr 2021 15:40:51
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Apr 2021 15:41:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Apr 2021 15:41:28
User entered '83' reason for change: Data Entry Error	Lisa Jackson (b) (4)	01 Apr 2021 15:41:28
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Apr 2021 15:40:51
User entered empty.	Lisa Jackson (b) (4)	01 Apr 2021 15:40:51
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 15:41:28
User entered empty.	System	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '10'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '148'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '81'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:40:51

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '01 Apr 2021'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '09:59'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:59'	System	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '97.3' F	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Other (Other)'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'TEMPORAL'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '81'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered missing code ND - Not Done.	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '111'	Lisa Jackson (b) (4)	01 Apr 2021 15:54:13
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '88'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:54:13

US3142043

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Apr 2021 15:41:54
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '01 Apr 2021'	Lisa Jackson (b) (4)	01 Apr 2021 15:41:54
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Apr 2021 15:42:36
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered empty.	Lisa Jackson (b) (4)	01 Apr 2021 15:42:36
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

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 19:08:30
	(b) (4)	
User entered empty.	Lisa Jackson (b) (4)	01 Apr 2021 15:42:36
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	01 Apr 2021 15:42:36
DataPoint set to visible.	System	23 Mar 2021 20:15:48

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '01 Apr 2021'	Lisa Jackson (b) (4)	01 Apr 2021 15:42:36
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '09:29'	Lisa Jackson (b) (4)	01 Apr 2021 15:42:36
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:29'	System	01 Apr 2021 15:42:36

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lisa Jackson (b) (4) (b) (4)	01 Apr 2021 15:42:36

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Apr 2021 15:42:36

US3142043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Apr 2021 15:42:36

US3142043

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	01 Apr 2021 15:42:43
	(b) (4)	

US3142043

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 15:42:43

US3142043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:00:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:50:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 22:57:38

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:20:49
User entered 'USA-US064-2021-mRNA-1273-P301000005'	System	22 Jan 2021 19:20:44
User entered 'New'	(b) (4), (b) (6)	22 Jan 2021 19:20:44

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
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)	21 Jan 2021 23:08:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 23:08:17
Data point term sent to Coder	System	21 Jan 2021 23:07:22
User entered 'COVID-19'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User closed query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' (Site from DM). User signature succeeded.	(b) (4)	20 Apr 2021 10:40:34
	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
Query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' answered with 'done' (Site from DM).	Jami Wagner (b) (4)	12 Apr 2021 20:17:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 20:14:38
User opened query 'Per CDM, Per Sponsor review: Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 08:59:12
	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '30 Nov 2020'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '12 Dec 2020'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:37:27
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with [study drug] from none to not applicable.' answered with 'corrected ' (Site from Safety).	Jill York (b) (4)	01 Mar 2021 17:57:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 17:57:29
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with [study drug] from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 20:37:28
User entered 'None (NONE)'	Shelby Pickle (b) (4) (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'I'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Shelby Pickle (b) (4)	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:00:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 20:14:38
User entered '0'	System	21 Jan 2021 23:07:04

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:25:04
Data point term sent to Coder	System	30 Mar 2021 21:24:25
User entered 'hypertension'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jami Wagner (b) (4)	07 Apr 2021 17:27:59
User entered 'No (N)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '20 Jan 2021'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'No (N)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

US3142043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Not Related (NOT RELATED)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Not Related (NOT RELATED)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'None (NONE)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'I'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '0'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Jami Wagner (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:21
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Narrative = SUBJECT DIAGNOSED WITH HYPERTENSION. Please confirm if this is a Medically Attended event. If yes, please update "Was this a medically-attended AE" field above. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 22:25:50
Query 'Per DM CLR: Narrative = SUBJECT DIAGNOSED WITH HYPERTENSION. Please confirm if this is a Medically Attended event. If yes, please update "Was this a medically-attended AE" field above.	Jami Wagner (b) (4) (b) (4)	07 Apr 2021 17:28:35
' answered with 'updated per query ' (Site from DM). User opened query 'Per DM CLR: Narrative = SUBJECT DIAGNOSED WITH HYPERTENSION. Please confirm if this is a Medically Attended event. If yes, please update "Was this a medically-attended AE" field above. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:09:02
User entered 'Subject diagnosed with hypertension and was prescribed hydrochlorthiazide per day 179 phone visit'	Jami Wagner (b) (4) (b) (4)	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 21:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:00:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 17:27:59
User entered '0'	System	30 Mar 2021 21:23:49

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:00:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:39:23
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:02:08
User entered 'Yes (Y)'	Meghan York (b) (4)	13 Nov 2020 18:34:44

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 18:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:37:46
Data point term sent to Coder	System	13 Nov 2020 18:36:30
User entered 'Atorvastatin'	Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'hypercholesterolemia'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '40'	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'mg (mg)'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 19:08:30
User entered empty.	Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'once daily (QD)'	(b) (4) Meghan York (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered empty.	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Oral (ORAL)'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered empty.	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'un Jun 2010'	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered '0'	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered empty.	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'No (N)'	Meghan York (b) (4)	13 Nov 2020 18:35:34
	(b) (4)	

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:35:34

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 17:18:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 17:18:40
Data point term sent to Coder Coding entries removed.	System Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 17:17:42 18 Mar 2021 17:16:41
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:03:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:21:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:21:10
Data point term sent to Coder User entered 'hydrochlorothazide'	System Jill York (b) (4)	01 Mar 2021 18:08:03 01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:18
User entered 'No (N)'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:40:58
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'AE added per query' (Site from DM).	Jami Wagner (b) (4) (b) (4)	30 Mar 2021 21:34:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:44:14
User closed query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:41:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:23:36
Query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'DATA CHANGED FOR MEDICATION TYPE.' (Site from DM).	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 17:17:06
User entered 'HYPERTENSION' reason for change: Data Entry Error	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 17:16:41
User opened query 'Per DM CLR: Please review the indication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 20:59:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'heart burn'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:24
User entered '25'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:26
User entered 'mg (mg)'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:28
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:35
User entered 'once daily (QD)'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:37
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:43
User entered 'Oral (ORAL)'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:48
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:04:04
User entered '20 Jan 2021'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:04:06
User entered '0'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:04:09
User entered 'Yes (Y)'	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:04:11
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:04:14
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 18:07:12
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 18:07:12
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:07:04
User entered empty.	Jill York (b) (4)	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 18:07:04

US3142043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:00:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
	(b) (4)	
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 17:49:33
	(b) (4)	

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'USA-US064-2021-MRNA-1273-P301000005'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Ripley'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Hollister'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Colorado Springs'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '80920'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
User entered 'US'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 19:38:27
User entered '1'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'USA-US064-2021-MRNA-1273-P301000005'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Ripley'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Hollister'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Colorado Springs'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '80920'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
User entered 'US'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 19:38:27
User entered '1'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:00:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
User entered '22/Jan/2021 19:21'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:00:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
User entered 'I'		22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'USA-US064-2021-MRNA-1273-P301000005'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'No (N)'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Ripley'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Hollister'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '4190 East Woodmen Road Suite 210'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered 'Colorado Springs'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
Reviewed for Safety.		22 Jan 2021 19:21:04
User entered '80920'	System	22 Jan 2021 19:20:44

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:28
User entered 'US'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:00:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 19:38:27
User entered '1'	System	22 Jan 2021 19:21:11

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:00:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered '02/Mar/2021 14:38'	(b) (4) System	02 Mar 2021 19:38:27

US3142043

Folder: SAE USA-US064-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:00:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 19:08:30
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 19:38:27