

US3412208 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:43:06

All time stamps listed in this document are displayed in GMT

US3412208

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

[Participant ID](#)

US3412208

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

US3412208

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:57:40

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	75
Age Units	YEARS
Age (Derived)	76
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) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:57:40

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Condition	ALLERGIC RHINITIS - SEASONAL
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Condition	HYPERLIPIDEMIA
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 (4)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Condition	OSTEOARTHRITIS (RIGHT KNEE)
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:57:40

Generated On: 11 Aug 2021 22:43:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:39
Height (xxx.x)	160 cm
Weight (xxx.x)	65.9 kg
BMI (xxx.x)	25.74219 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 13 Feb 2021 04:57:40

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:57:40

Generated On: 11 Aug 2021 22:43:06

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

WORKOUTS AT GYM, GOES TO CHURCH WITH LARGE GATHERINGS, DOES VOLUNTEER WORK WITH SOCIAL INTERACTIONS, GOES TO GROCERY STORE

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:57:40

Generated On: 11 Aug 2021 22:43:06

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185622

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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)	11 AUG 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:39
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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)	11 AUG 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 16:40 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 16:40

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) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 AUG 2020
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Collection time (00:00-23:59)	16:04 (24 HR)
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Collection date and time (derived)	11 AUG 2020 16:04
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:09	11 AUG 2020 16:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:16

PC Open Date & Time

11 AUG 2020 17:00

PC Close Date & Time

11 AUG 2020 19:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 AUG 2020 20:38
PC Open Date & Time	11 AUG 2020 20:25
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:16

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:20

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

16 AUG 2020 21:21

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 19:21

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

11 AUG 2020 17:18

PC Open Date & Time

11 AUG 2020 17:00

PC Close Date & Time

11 AUG 2020 19:30

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 20:39

PC Open Date & Time

11 AUG 2020 20:25

PC Close Date & Time

12 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:16

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

13 AUG 2020 19:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

14 AUG 2020 19:17

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

15 AUG 2020 19:20

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

16 AUG 2020 21:21

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

17 AUG 2020 19:21

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 17:19
PC Open Date & Time	11 AUG 2020 17:00
PC Close Date & Time	11 AUG 2020 19:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 20:39
PC Open Date & Time	11 AUG 2020 20:25
PC Close Date & Time	12 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

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)

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US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 19:17
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

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EAB) (1725)

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

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 ☒

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 19:17
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

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 ☒

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EAB) (1725)

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:21
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:22
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

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)

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 19:22
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3412208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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)	8 SEP 2020
Time of assessment (00:00-23:59)	08:34 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 08:34
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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)	8 SEP 2020
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 09:59
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 09:25 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 09:25

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

US3412208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

08:47 (24 HR)

Collection date and time (derived)

08 SEP 2020 08:47

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:49	08 SEP 2020 08:49
Nasopharyngeal Swab 2	No		

US3412208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

08 SEP 2020 10:01

PC Open Date & Time

08 SEP 2020 09:45

PC Close Date & Time

08 SEP 2020 12:15

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	08 SEP 2020 19:20
PC Open Date & Time	08 SEP 2020 13:10
PC Close Date & Time	09 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

09 SEP 2020 19:27

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

12 SEP 2020 19:19

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

13 SEP 2020 19:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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 ☐

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

4

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 10:03

PC Open Date & Time

08 SEP 2020 09:45

PC Close Date & Time

08 SEP 2020 12:15

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:22

PC Open Date & Time

08 SEP 2020 13:10

PC Close Date & Time

09 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:27

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

10 SEP 2020 19:22

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

11 SEP 2020 19:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

12 SEP 2020 19:19

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

13 SEP 2020 19:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

14 SEP 2020 20:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:04
PC Open Date & Time	08 SEP 2020 09:45
PC Close Date & Time	08 SEP 2020 12:15

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:23
PC Open Date & Time	08 SEP 2020 13:10
PC Close Date & Time	09 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

		Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 19:28	
PC Open Date & Time	09 SEP 2020 12:00	
PC Close Date & Time	10 SEP 2020 11:59	

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

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 ☒

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:22
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

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 ☒

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

100 of 2834

EAB) (1725)

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:20
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

102 of 2834

EAB) (1725)

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:43
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

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 ☒

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:42
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3412208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:57:39

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:46:12

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

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) _____

US3412208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3412208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	08:02 (24 HR)
Collection date and time (derived)	06 OCT 2020 08:02

US3412208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:46:13

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 09:02:35
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

20 OCT 2020 09:31:07

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

27 OCT 2020 09:30:50

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

10 NOV 2020 09:31:25

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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	17 NOV 2020 09:30:53
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 103

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

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 07:55:14

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have 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 checked="" 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)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 DEC 2020 09:31:54
Patient Cloud Open Date & Time	10 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	127 of 2834

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have 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 checked="" 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)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 DEC 2020 09:31:28
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 DEC 2020 09:30:56
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

07 JAN 2021 04:20:35

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

16 JAN 2021 12:56:37

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 10:06:57

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

28 JAN 2021 09:30:35

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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	04 FEB 2021 09:34:58
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 <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 FEB 2021 09:31:22
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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	18 FEB 2021 09:30:40
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 09:30:42

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

11 MAR 2021 09:31:00

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:31:52

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 09:31:05

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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	01 APR 2021 09:47:44
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 09:31:05

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 09:43:49

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

22 APR 2021 09:30:49

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

29 APR 2021 09:32:30

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 292

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

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

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

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

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

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

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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="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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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="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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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14 FEB 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 MAR 2022 00:01

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07 MAR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 <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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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17 MAR 2022 00:01

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21 MAR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

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28 MAR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

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25 APR 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 <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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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°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 ☐

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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 ☐ Yes ☐

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

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3412208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:43:06

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		11 MAR 2021 09:30:47

US3412208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:36:13

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:36:12

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 08:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

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.

US3412208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	08:34 (24 HR)
Collection date and time (derived)	04 MAR 2021 08:34

US3412208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Date of Contact	10 DEC 2020
Time of Contact	12:35
Date and Time of Contact (derived)	10 DEC 2020 12:35
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>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	6 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 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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	37.0 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	94 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	96 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	False	
O2 Saturation	96 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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	95 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" 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 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 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 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 DEC 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	98.9 F
-------------	--------

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

Cough	None <input 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 (15)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (16)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 (17)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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 (17)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

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Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" 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 (18)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

	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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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"/>

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Date of Visit 10 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 10 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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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 13 DEC 2020

End Date 16 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 _____

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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EAB) (1725)

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US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	16 DEC 2020
Day 9	Yes	18 DEC 2020
Day 14	Yes	23 DEC 2020
Day 21	No	
Day 28	Yes	19 JAN 2021

US3412208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 DEC 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 12:40
Height (xxx.x)	161 cm
Weight (xxx.x)	61 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412208

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3412208

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 11:26
Height (xxx.x)	160.5 cm
Weight (xxx.x)	65.5 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3412208

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:41:22

Generated On: 11 Aug 2021 22:43:06

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 JAN 2021

US3412208

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	UNBLND_DECIDE

US3412208

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

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>)	7 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

US3412208

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Height	160.5 cm
Weight	65.5 kg
BMI (xxx.x)	25.42677

US3412208

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Height	160.5 cm
Weight	65.5 kg
BMI (xxx.x)	25.42677
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)	7 JAN 2021
Time of assessment (00:00-23:59)	9:31 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 9:31
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Height	160.5 cm
Weight	65.5 kg
BMI (xxx.x)	25.42677
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)	7 JAN 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 10:10
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 JAN 2021

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

US3412208

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

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) 7 JAN 2021

What was the treatment time? (00:00-23:59) 9:43 (24 HR)

Treatment Date and Time (derived) 7 JAN 2021 9:43

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

US3412208

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

9:38 (24 HR)

Collection date and time (derived)

7 JAN 2021 9:38

US3412208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	9:36
Collection Date and Time (derived)	7 JAN 2021 9:36

US3412208

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:36:13

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:36:13

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

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)	4 FEB 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 08:52
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

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)	4 FEB 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 10:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3412208

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3412208

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 09:39 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 09:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3412208

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:36:13

Generated On: 11 Aug 2021 22:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:36:13

Generated On: 11 Aug 2021 22:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412208

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:16 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 08:16
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:23

Generated On: 11 Aug 2021 22:43:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	08:34 (24 HR)
Collection date and time (derived)	04 MAR 2021 08:34

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:35:25

Generated On: 11 Aug 2021 22:43:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:35:25

Generated On: 11 Aug 2021 22:43:06

AEID	USA-US061-2020-MRNA-1273-P30 1000017
Adverse event	SYMPTOMATIC 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)	06 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 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) 15 Mar 2021 15:35:25

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:35:25

Generated On: 11 Aug 2021 22:43:06

SUBJECT PRESENTED WITH AN ILLNESS THAT HAD AN ONSET OF 06-DEC-2020. SUBJECT PRESENTED WITH MILD COUGH, MODERATE FATIGUE, MILD BODY ACHES, MILD HEADACHES, MODERATE LOSS OF TASTE AND SMELL, MODERATE RUNNY NOSE, AND MILD NAUSEA. THESE SYMPTOMS HAVE IMPROVED AND SUBJECTS HUSBAND DID TEST POSITIVE FOR COVID-19. SUBJECT HAS NOT TAKEN ANY MEDICATIONS AND HAS NOT HAD ANY TREATMENT OUTSIDE OF BEING TESTED BY OUR SITE. ALL SYMPTOMS WERE RESOLVED BY 23-DEC-2020

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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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 15:35:25

Generated On: 11 Aug 2021 22:43:06

AEID	
Adverse event	INSOMNIA
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)	24 NOV 2020
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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 15:35:25

Generated On: 11 Aug 2021 22:43:06

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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) _____	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:39:20

Generated On: 11 Aug 2021 22:43:06

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS KNEE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication VITAMIN D 3

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH / BONE
HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication DICLOFENAC 170 GEL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES FOR SEASONAL ALLERGIES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication TRIAMCINOLONE

Prophylaxis Yes ☐
No ☒

Indication RASH FROM MASK

Dose per administration 0.1

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

If dose unit is Other, specify %

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION PAIN LEFT
SHOULDER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:21:25

Generated On: 11 Aug 2021 22:43:06

	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)		04 FEB 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:39:20

Generated On: 11 Aug 2021 22:43:06

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:43:06

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

US3412208

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:43:06

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 ☐

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/DEC/2020 07:59
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

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/DEC/2020 16:53
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

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/DEC/2020 12:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/JAN/2021 18:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/FEB/2021 08:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/FEB/2021 08:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Apr 2021 14:41:24

Generated On: 11 Aug 2021 22:43:06

SAEID	USA-US061-2020-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/MAR/2021 14:01
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

US3412208 (Prod: New Horizons Clinical Research)

US3412208

Form: Participant Creation

Generated On: 11 Aug 2021 22:43:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'US3412208'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:09:14

US3412208

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 20:44:28

US3412208

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:09:16

US3412208

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[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 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	11 Aug 2020 20:44:28

US3412208

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'SCRN'	System	11 Aug 2020 20:44:28

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:09:17

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '75'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'YEARS'	System	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '76'	System	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Female (F)'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'I'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 20:44:45

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '11 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Aug 2020'	System	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '2020'	System	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:05

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:09:16

US3412208

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'I'	System	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:43:06

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:43:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:16

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:53:37
Data point term sent to Coder	System	14 Oct 2020 18:52:25
Coding entries removed.	Melissa Fuson (b) (4)	14 Oct 2020 18:51:40
User entered 'ALLERGIC RHINITIS - SEASONAL' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Oct 2020 18:51:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:53:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:53:32
Data point term sent to Coder	System	20 Aug 2020 22:52:56
User entered 'Seasonal Allergic Rhinitis'	(b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'UN UNK 1950'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Jan 1950'	System	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '1950'	System	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:52:39

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:55:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:55:24
Data point term sent to Coder	System	20 Aug 2020 22:53:57
User entered 'Hypothyroidism'	(b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Jan 2019'	System	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '2019'	System	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:52:58

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:55:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 22:55:23
Data point term sent to Coder	System	20 Aug 2020 22:53:57
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Jan 2010'	System	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '2010'	System	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:53:26

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:10:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:10:21
Data point term sent to Coder	System	20 Aug 2020 22:53:57
User entered 'Osteoarthritis (right knee)'	(b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Jan 2002'	System	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '2002'	System	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	20 Aug 2020 22:53:46

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 19:01:43
Data point term sent to Coder	System	14 Oct 2020 18:30:18
User entered 'POST-MENOPAUSAL'	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'I'	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Melissa Fuson (b) (4)	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	14 Oct 2020 18:30:08

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Facial rash - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 13:39:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:39:57
Data point term sent to Coder	System	19 Oct 2020 13:51:44
User entered 'rash from mask'	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'un UNK 2020'	Jacob sekinger (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Jacob sekinger (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	Jacob sekinger (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	Jacob sekinger (b) (4)	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'Jan 2020'	System	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '2020'	System	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered empty.	System	19 Oct 2020 13:51:14

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered 'No (N)'		20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 17:53:41
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '15:39' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered empty.		20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '11 Aug 2020 15:39'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '160' cm reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered empty.		20 Aug 2020 22:53:52
DataPoint set to visible.	System	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '65.9' kg reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered empty.		20 Aug 2020 22:53:52
DataPoint set to visible.	System	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
Amendment Manager: User entered '25.74219'	System	16 Sep 2020 23:52:19
User entered '25.7'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52
DataPoint set to visible.	System	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'kg/m2'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52
DataPoint set to visible.	System	11 Aug 2020 20:45:10

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 17:53:41
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 17:53:41
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'bpm'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered empty.		20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'breaths/min'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:53:41
User entered empty.		20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'mmHg'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 17:53:41
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'mmHg'	System	21 Aug 2020 17:53:41
User entered empty.	System	20 Aug 2020 22:53:52

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50

US3412208

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50

US3412208

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:54:08

US3412208

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:07:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 12:58:44
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	20 Aug 2020 22:54:20
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	20 Aug 2020 22:54:20
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 22:54:20
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	20 Aug 2020 22:54:08
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 22:54:08

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 04:03:13
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'CLIENT IS POST-MENOPAUSAL' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Oct 2020 18:32:18
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	14 Oct 2020 18:31:19
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	14 Oct 2020 18:30:53
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Oct 2020 18:30:53
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:36:05
User entered 'Surgically sterile (SURGICALLY STERILE)'		20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Oct 2020 18:31:19
User closed query 'Date of surgery is provided, however, date of surgery unknown is checked. Please correct.' (Site from System).	System	20 Aug 2020 22:56:16
User opened query 'Date of surgery is provided, however, date of surgery unknown is checked. Please correct.' (Site from System).	System	20 Aug 2020 22:56:01
User entered 'UN UNK 1972'	(b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 22:56:16
User entered '1'		20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	(b) (4)	14 Oct 2020 18:31:57
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:30:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	14 Oct 2020 18:31:57
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	20 Aug 2020 22:56:01

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Workouts at gym, goes to church with large gatherings, does volunteer work with social interactions, goes to grocery store'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:59:36

US3412208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:25

US3412208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 20:45:25

US3412208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Home (Home)'	Steven Anderson (b) (4)	11 Aug 2020 20:45:25

US3412208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'VISIT1'	System	11 Aug 2020 20:45:25

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:14:45

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:40:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:40:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 20:14:45
User entered '185622' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:14:45

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 20:14:45

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

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)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:05

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

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)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:05

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:05

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:05

US3412208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:05

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:54:36
User entered '160' cm		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:54:36
User entered '65.9' kg		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 17:54:36
User entered '160' cm	(b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:54:36
User entered '65.9' kg		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '15:39'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '11 Aug 2020 15:39'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '68'	(b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'bpm'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'breaths/min'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '108'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Per CDM: Please indicate if this value should be considered as CS or NCS. If CS, please report as AE as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 04:10:33
Query 'Per CDM: Please indicate if this value should be considered as CS or NCS. If CS, please report as AE as appropriate. ' answered with 'NCS NO AE NEEDED' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 17:09:01
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 06:47:12
User opened query 'Per CDM: Please indicate if this value should be considered as CS or NCS. If CS, please report as AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 06:47:11
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per protocol, within normal range. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 16:58:09
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:52:19
User entered '58'	(b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:54:36
User entered '160' cm		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 17:54:36
User entered '65.9' kg		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:40:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol post-dose vital signs only need to be >30 minutes post injection' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 23:16:05
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 23:15:39
User entered '17:10'	(b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '11 Aug 2020 17:10'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '98.1' F	(b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '64'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'bpm'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '14'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'breaths/min'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '104'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '62'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	20 Aug 2020 23:15:39

US3412208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:16:10

US3412208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:16:10

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

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)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '16:40'	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '11 Aug 2020 16:40'	System	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'ONCE'	System	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 20:46:37

US3412208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:16:33

US3412208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:16:33

US3412208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '16:04'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:16:33

US3412208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '11 Aug 2020 16:04'	System	20 Aug 2020 23:16:33

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '16:09'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '11 Aug 2020 16:09'	System	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	20 Aug 2020 23:19:16

US3412208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:20:49

US3412208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	20 Aug 2020 23:20:49

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:16:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd904c446-ec9a-4311-8371-e99a633edb19'	System	11 Aug 2020 21:16:55
User entered 'Yes (Y)'	System	11 Aug 2020 21:16:55

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:16:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd904c446-ec9a-4311-8371-e99a633edb19'	System	11 Aug 2020 21:16:55
User entered '98.1'	System	11 Aug 2020 21:16:55

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:16:36', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd904c446-ec9a-4311-8371-e99a633edb19'	System	11 Aug 2020 21:16:55
User entered 'No (N)'	System	11 Aug 2020 21:16:55

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:16:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd904c446-ec9a-4311-8371-e99a633edb19'	System	11 Aug 2020 21:16:55
User entered '11 Aug 2020 17:16'	System	11 Aug 2020 21:16:55

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 17:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 19:30'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:36:42', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fbe45c18-8ed3-4bd3-bef5-5cf2eccc03c7'	System	12 Aug 2020 00:38:27
User entered 'Yes (Y)'	System	12 Aug 2020 00:38:27

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fbe45c18-8ed3-4bd3-bef5-5cf2eccc03c7'	System	12 Aug 2020 00:38:27
User entered '97.9'	System	12 Aug 2020 00:38:27

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fbe45c18-8ed3-4bd3-bef5-5cf2eccc03c7'	System	12 Aug 2020 00:38:27
User entered 'No (N)'	System	12 Aug 2020 00:38:27

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:24', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fbe45c18-8ed3-4bd3-bef5-5cf2eccc03c7'	System	12 Aug 2020 00:38:27
User entered '11 Aug 2020 20:38'	System	12 Aug 2020 00:38:27

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 20:25'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 2'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:15:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fc22d798-c9b3-40cc-80fb-2ce29c569762'	System	12 Aug 2020 23:16:08
User entered 'Yes (Y)'	System	12 Aug 2020 23:16:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:15:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fc22d798-c9b3-40cc-80fb-2ce29c569762'	System	12 Aug 2020 23:16:08
User entered '98.2'	System	12 Aug 2020 23:16:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:15:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fc22d798-c9b3-40cc-80fb-2ce29c569762'	System	12 Aug 2020 23:16:08
User entered 'No (N)'	System	12 Aug 2020 23:16:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:03', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fc22d798-c9b3-40cc-80fb-2ce29c569762'	System	12 Aug 2020 23:16:08
User entered '12 Aug 2020 19:16'	System	12 Aug 2020 23:16:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 3'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:15:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1285f10d-cbf2-4c50-8482-67ac291d3489'	System	13 Aug 2020 23:16:01
User entered 'Yes (Y)'	System	13 Aug 2020 23:16:01

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:15:26', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1285f10d-cbf2-4c50-8482-67ac291d3489'	System	13 Aug 2020 23:16:01
User entered '98.3'	System	13 Aug 2020 23:16:01

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:15:29', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1285f10d-cbf2-4c50-8482-67ac291d3489'	System	13 Aug 2020 23:16:01
User entered 'No (N)'	System	13 Aug 2020 23:16:01

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:15:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1285f10d-cbf2-4c50-8482-67ac291d3489'	System	13 Aug 2020 23:16:01
User entered '13 Aug 2020 19:15'	System	13 Aug 2020 23:16:01

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 4'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c2ccdf98-aabd-489e-9c7a-7b4a68f82c40'	System	14 Aug 2020 23:16:25
User entered 'Yes (Y)'	System	14 Aug 2020 23:16:25

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c2ccdf98-aabd-489e-9c7a-7b4a68f82c40'	System	14 Aug 2020 23:16:25
User entered '98.2'	System	14 Aug 2020 23:16:25

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c2ccdf98-aabd-489e-9c7a-7b4a68f82c40'	System	14 Aug 2020 23:16:25
User entered 'No (N)'	System	14 Aug 2020 23:16:25

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c2ccdf98-aabd-489e-9c7a-7b4a68f82c40'	System	14 Aug 2020 23:16:25
User entered '14 Aug 2020 19:16'	System	14 Aug 2020 23:16:25

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 5'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:19:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '67d3705b-521c-4d0a-af20-1f7598442786'	System	15 Aug 2020 23:20:08
User entered 'Yes (Y)'	System	15 Aug 2020 23:20:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:19:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '67d3705b-521c-4d0a-af20-1f7598442786'	System	15 Aug 2020 23:20:08
User entered '98.0'	System	15 Aug 2020 23:20:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:19:59', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '67d3705b-521c-4d0a-af20-1f7598442786'	System	15 Aug 2020 23:20:08
User entered 'No (N)'	System	15 Aug 2020 23:20:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:05', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '67d3705b-521c-4d0a-af20-1f7598442786'	System	15 Aug 2020 23:20:08
User entered '15 Aug 2020 19:20'	System	15 Aug 2020 23:20:08

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 6'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:19:29', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '324fa8df-46f0-454b-b882-3c09c1886137'	System	17 Aug 2020 01:21:29
User entered 'Yes (Y)'	System	17 Aug 2020 01:21:29

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '324fa8df-46f0-454b-b882-3c09c1886137'	System	17 Aug 2020 01:21:29
User entered '97.3'	System	17 Aug 2020 01:21:29

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '324fa8df-46f0-454b-b882-3c09c1886137'	System	17 Aug 2020 01:21:29
User entered 'No (N)'	System	17 Aug 2020 01:21:29

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:23', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '324fa8df-46f0-454b-b882-3c09c1886137'	System	17 Aug 2020 01:21:29
User entered '16 Aug 2020 21:21'	System	17 Aug 2020 01:21:29

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 7'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9c79ad4b-dde2-4654-b697-8f1520360311'	System	17 Aug 2020 23:21:28
User entered 'Yes (Y)'	System	17 Aug 2020 23:21:28

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9c79ad4b-dde2-4654-b697-8f1520360311'	System	17 Aug 2020 23:21:28
User entered '98.3'	System	17 Aug 2020 23:21:28

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9c79ad4b-dde2-4654-b697-8f1520360311'	System	17 Aug 2020 23:21:28
User entered 'No (N)'	System	17 Aug 2020 23:21:28

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:23', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9c79ad4b-dde2-4654-b697-8f1520360311'	System	17 Aug 2020 23:21:28
User entered '17 Aug 2020 19:21'	System	17 Aug 2020 23:21:28

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:13', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0bf701a5-b7b9-48b4-b835-cd59e0c52c89'	System	11 Aug 2020 21:18:38
User entered 'None (1)'	System	11 Aug 2020 21:18:38

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0bf701a5-b7b9-48b4-b835-cd59e0c52c89'	System	11 Aug 2020 21:18:38
User entered 'No (N)'	System	11 Aug 2020 21:18:38

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:21', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0bf701a5-b7b9-48b4-b835-cd59e0c52c89'	System	11 Aug 2020 21:18:38
User entered 'No (N)'	System	11 Aug 2020 21:18:38

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0bf701a5-b7b9-48b4-b835-cd59e0c52c89'	System	11 Aug 2020 21:18:38
User entered 'None (1)'	System	11 Aug 2020 21:18:38

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0bf701a5-b7b9-48b4-b835-cd59e0c52c89'	System	11 Aug 2020 21:18:38
User entered '11 Aug 2020 17:18'	System	11 Aug 2020 21:18:38

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 17:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 19:30'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8d73acd3-d728-40fe-b793-23fd94e1ca6d'	System	12 Aug 2020 00:39:06
User entered 'None (1)'	System	12 Aug 2020 00:39:06

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8d73acd3-d728-40fe-b793-23fd94e1ca6d'	System	12 Aug 2020 00:39:06
User entered 'No (N)'	System	12 Aug 2020 00:39:06

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8d73acd3-d728-40fe-b793-23fd94e1ca6d'	System	12 Aug 2020 00:39:06
User entered 'No (N)'	System	12 Aug 2020 00:39:06

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:38:59', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8d73acd3-d728-40fe-b793-23fd94e1ca6d'	System	12 Aug 2020 00:39:06
User entered 'None (1)'	System	12 Aug 2020 00:39:06

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8d73acd3-d728-40fe-b793-23fd94e1ca6d'	System	12 Aug 2020 00:39:06
User entered '11 Aug 2020 20:39'	System	12 Aug 2020 00:39:06

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 20:25'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 2'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc63e702-137e-414b-9ab4-461dd55303bf'	System	12 Aug 2020 23:16:36
User entered 'None (1)'	System	12 Aug 2020 23:16:36

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc63e702-137e-414b-9ab4-461dd55303bf'	System	12 Aug 2020 23:16:36
User entered 'No (N)'	System	12 Aug 2020 23:16:36

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:18', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc63e702-137e-414b-9ab4-461dd55303bf'	System	12 Aug 2020 23:16:36
User entered 'No (N)'	System	12 Aug 2020 23:16:36

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:21', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc63e702-137e-414b-9ab4-461dd55303bf'	System	12 Aug 2020 23:16:36
User entered 'None (1)'	System	12 Aug 2020 23:16:36

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:32', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc63e702-137e-414b-9ab4-461dd55303bf'	System	12 Aug 2020 23:16:36
User entered '12 Aug 2020 19:16'	System	12 Aug 2020 23:16:36

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 3'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:01', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bd82fbed-2b79-4513-9a4b-5998456135f0'	System	13 Aug 2020 23:16:31
User entered 'None (1)'	System	13 Aug 2020 23:16:31

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:04', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bd82fbed-2b79-4513-9a4b-5998456135f0'	System	13 Aug 2020 23:16:31
User entered 'No (N)'	System	13 Aug 2020 23:16:31

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:18', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bd82fbed-2b79-4513-9a4b-5998456135f0'	System	13 Aug 2020 23:16:31
User entered 'No (N)'	System	13 Aug 2020 23:16:31

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bd82fbed-2b79-4513-9a4b-5998456135f0'	System	13 Aug 2020 23:16:31
User entered 'None (1)'	System	13 Aug 2020 23:16:31

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:26', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bd82fbed-2b79-4513-9a4b-5998456135f0'	System	13 Aug 2020 23:16:31
User entered '13 Aug 2020 19:16'	System	13 Aug 2020 23:16:31

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 4'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:31', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cdac45ae-1b01-4f8c-bfe3-c1bd2edaa01d'	System	14 Aug 2020 23:17:11
User entered 'None (1)'	System	14 Aug 2020 23:17:11

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cdac45ae-1b01-4f8c-bfe3-c1bd2edaa01d'	System	14 Aug 2020 23:17:11
User entered 'No (N)'	System	14 Aug 2020 23:17:11

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cdac45ae-1b01-4f8c-bfe3-c1bd2edaa01d'	System	14 Aug 2020 23:17:11
User entered 'No (N)'	System	14 Aug 2020 23:17:11

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:16:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cdac45ae-1b01-4f8c-bfe3-c1bd2edaa01d'	System	14 Aug 2020 23:17:11
User entered 'None (1)'	System	14 Aug 2020 23:17:11

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cdac45ae-1b01-4f8c-bfe3-c1bd2edaa01d'	System	14 Aug 2020 23:17:11
User entered '14 Aug 2020 19:17'	System	14 Aug 2020 23:17:11

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 5'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '413ceb2f-af18-461b-b43a-d703d769021a'	System	15 Aug 2020 23:20:44
User entered 'None (1)'	System	15 Aug 2020 23:20:44

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:20', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '413ceb2f-af18-461b-b43a-d703d769021a'	System	15 Aug 2020 23:20:44
User entered 'No (N)'	System	15 Aug 2020 23:20:44

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:23', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '413ceb2f-af18-461b-b43a-d703d769021a'	System	15 Aug 2020 23:20:44
User entered 'No (N)'	System	15 Aug 2020 23:20:44

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:27', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '413ceb2f-af18-461b-b43a-d703d769021a'	System	15 Aug 2020 23:20:44
User entered 'None (1)'	System	15 Aug 2020 23:20:44

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '413ceb2f-af18-461b-b43a-d703d769021a'	System	15 Aug 2020 23:20:44
User entered '15 Aug 2020 19:20'	System	15 Aug 2020 23:20:44

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 6'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:29', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '42bceb63-b5f3-48f6-9b1a-fc869252c4b2'	System	17 Aug 2020 01:22:02
User entered 'None (1)'	System	17 Aug 2020 01:22:02

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:34', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '42bceb63-b5f3-48f6-9b1a-fc869252c4b2'	System	17 Aug 2020 01:22:02
User entered 'No (N)'	System	17 Aug 2020 01:22:02

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '42bceb63-b5f3-48f6-9b1a-fc869252c4b2'	System	17 Aug 2020 01:22:02
User entered 'No (N)'	System	17 Aug 2020 01:22:02

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '42bceb63-b5f3-48f6-9b1a-fc869252c4b2'	System	17 Aug 2020 01:22:02
User entered 'None (1)'	System	17 Aug 2020 01:22:02

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:21:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '42bceb63-b5f3-48f6-9b1a-fc869252c4b2'	System	17 Aug 2020 01:22:02
User entered '16 Aug 2020 21:21'	System	17 Aug 2020 01:22:02

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 7'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:32', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd42c5458-01ed-4300-a8f2-e1623157b99d'	System	17 Aug 2020 23:21:55
User entered 'None (1)'	System	17 Aug 2020 23:21:55

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:36', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd42c5458-01ed-4300-a8f2-e1623157b99d'	System	17 Aug 2020 23:21:55
User entered 'No (N)'	System	17 Aug 2020 23:21:55

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:38', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd42c5458-01ed-4300-a8f2-e1623157b99d'	System	17 Aug 2020 23:21:55
User entered 'No (N)'	System	17 Aug 2020 23:21:55

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd42c5458-01ed-4300-a8f2-e1623157b99d'	System	17 Aug 2020 23:21:55
User entered 'None (1)'	System	17 Aug 2020 23:21:55

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd42c5458-01ed-4300-a8f2-e1623157b99d'	System	17 Aug 2020 23:21:55
User entered '17 Aug 2020 19:21'	System	17 Aug 2020 23:21:55

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:18:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'None (0)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered 'No (N)'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T17:19:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2f1bb26b-4e89-42df-b441-7333cc5b4e20'	System	11 Aug 2020 21:19:44
User entered '11 Aug 2020 17:19'	System	11 Aug 2020 21:19:44

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 17:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 19:30'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'None (0)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered 'No (N)'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-11T20:39:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '05150bc7-d0da-44ea-b2b1-add4eafaeef0'	System	12 Aug 2020 00:39:30
User entered '11 Aug 2020 20:39'	System	12 Aug 2020 00:39:30

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Aug 2020 20:25'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 2'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'None (0)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:16:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered 'No (N)'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-12T19:17:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '785e8f1a-958f-4508-8d2a-c0e762aae6f4'	System	12 Aug 2020 23:17:08
User entered '12 Aug 2020 19:17'	System	12 Aug 2020 23:17:08

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 3'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:31', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:36', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:38', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'None (0)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered 'No (N)'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-13T19:16:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a5f3d40d-93dd-4c77-a013-28497a904525'	System	13 Aug 2020 23:17:00
User entered '13 Aug 2020 19:16'	System	13 Aug 2020 23:17:00

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 4'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:24', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'None (0)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:28', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered 'No (N)'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-14T19:17:35', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2834295f-c0b1-415c-b12a-c9dc98fb97e3'	System	14 Aug 2020 23:17:39
User entered '14 Aug 2020 19:17'	System	14 Aug 2020 23:17:39

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 5'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:20:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'None (0)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:21:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered 'No (N)'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-15T19:21:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cb6ebc7a-8c4a-4e04-9749-417ad0f29a0d'	System	15 Aug 2020 23:21:11
User entered '15 Aug 2020 19:21'	System	15 Aug 2020 23:21:11

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 6'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:04', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:13', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'None (0)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:18', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered 'No (N)'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-16T21:22:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b9e60f33-660a-4e9b-a889-b8087c291432'	System	17 Aug 2020 01:22:29
User entered '16 Aug 2020 21:22'	System	17 Aug 2020 01:22:29

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 7'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:21:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:05', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'None (0)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered 'No (N)'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-08-17T19:22:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'cd808898-76c6-4f8f-af2b-603376d85ccf'	System	17 Aug 2020 23:22:22
User entered '17 Aug 2020 19:22'	System	17 Aug 2020 23:22:22

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:46:37

US3412208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:21:07

US3412208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:21:07

US3412208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:21:07

US3412208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4)	20 Aug 2020 23:21:07
	(b) (4), (b) (6)	

US3412208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 23:21:12

US3412208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	20 Aug 2020 23:21:12

US3412208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:29:35

US3412208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:29:35

US3412208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:29:35

US3412208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:29:35

US3412208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:29:40

US3412208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	25 Aug 2020 17:29:40

US3412208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:13:43

US3412208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:13:43

US3412208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:13:43

US3412208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:13:43

US3412208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:13:48

US3412208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	01 Sep 2020 15:13:48

US3412208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:58:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:58:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:58:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'VISIT2'	System	08 Sep 2020 12:58:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 17:01:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Sep 2020 17:01:17
User entered '08:34' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:17
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 16:59:27
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '8 Sep 2020 08:34'	System	23 Sep 2020 17:01:17
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	23 Sep 2020 17:01:24
User entered '36.2' C reason for change: Data Entry Error	System	23 Sep 2020 17:01:24
User entered '36.2' C reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	23 Sep 2020 17:01:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 17:01:05
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 17:01:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:01:05
User entered '36.2' (non-conformant).	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 16:59:27
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:01:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:01:05
User entered '62' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'bpm'	System	23 Sep 2020 17:01:05
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:01:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:01:05
User entered '16' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'breaths/min'	System	23 Sep 2020 17:01:05
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:01:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:01:05
User entered '108' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	23 Sep 2020 17:01:05
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:01:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:01:05
User entered '60' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:01:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	23 Sep 2020 17:01:05
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 17:02:46
User entered '8 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 16:59:27
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:02:46
User entered '09:59' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '8 Sep 2020 09:59'	System	23 Sep 2020 17:02:46
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:02:46
User entered '97.3' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:02:46
User entered '54' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'bpm'	System	23 Sep 2020 17:02:46
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System	System	23 Sep 2020 17:02:46
data change (Site from System).		
User entered '12' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'breaths/min'	System	23 Sep 2020 17:02:46
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:02:46
User entered '118' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	23 Sep 2020 17:02:46
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 17:02:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Sep 2020 17:02:46
User entered '80' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:02:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Sep 2020 16:59:27
User entered empty.	System	23 Sep 2020 16:59:27
	Jacob sekinger (b) (4)	23 Sep 2020 16:59:27
	(b) (4)	

US3412208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'mmHg'	System	23 Sep 2020 17:02:46
User entered empty.	System	23 Sep 2020 16:59:27

US3412208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 17:02:59

US3412208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 17:02:59

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

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)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '09:25'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '08 Sep 2020 09:25'	System	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'ONCE'	System	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 13:32:41

US3412208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:14

US3412208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:14

US3412208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08:47' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 17:03:58
User entered '09:59'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:14

US3412208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '08 Sep 2020 08:47'	System	23 Sep 2020 17:03:58
User entered '08 Sep 2020 09:59'	System	23 Sep 2020 17:03:14

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08:49'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '08 Sep 2020 08:49'	System	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	23 Sep 2020 17:03:44

US3412208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:02

US3412208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	15 Sep 2020 13:53:02

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:01:32', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7652fbb-dc01-43b4-a09f-98ef3aa4010f'	System	08 Sep 2020 14:01:59
User entered 'Yes (Y)'	System	08 Sep 2020 14:01:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:01:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7652fbb-dc01-43b4-a09f-98ef3aa4010f'	System	08 Sep 2020 14:01:59
User entered '97.3'	System	08 Sep 2020 14:01:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:01:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7652fbb-dc01-43b4-a09f-98ef3aa4010f'	System	08 Sep 2020 14:01:59
User entered 'No (N)'	System	08 Sep 2020 14:01:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:01:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7652fbb-dc01-43b4-a09f-98ef3aa4010f'	System	08 Sep 2020 14:01:59
User entered '08 Sep 2020 10:01'	System	08 Sep 2020 14:01:59

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 09:45'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 12:15'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:20:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8acd2aad-50d2-4421-bc00-93b08bee53d2'	System	08 Sep 2020 23:20:47
User entered 'Yes (Y)'	System	08 Sep 2020 23:20:47

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:20:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8acd2aad-50d2-4421-bc00-93b08bee53d2'	System	08 Sep 2020 23:20:47
User entered '97.1'	System	08 Sep 2020 23:20:47

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:20:36', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8acd2aad-50d2-4421-bc00-93b08bee53d2'	System	08 Sep 2020 23:20:47
User entered 'No (N)'	System	08 Sep 2020 23:20:47

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:20:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8acd2aad-50d2-4421-bc00-93b08bee53d2'	System	08 Sep 2020 23:20:47
User entered '08 Sep 2020 19:20'	System	08 Sep 2020 23:20:47

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 13:10'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 2'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:26:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '5a156018-c5c9-4ccc-a977-abe21513013a'	System	09 Sep 2020 23:27:05
User entered 'Yes (Y)'	System	09 Sep 2020 23:27:05

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:26:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '5a156018-c5c9-4ccc-a977-abe21513013a'	System	09 Sep 2020 23:27:05
User entered '97.9'	System	09 Sep 2020 23:27:05

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:26:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '5a156018-c5c9-4ccc-a977-abe21513013a'	System	09 Sep 2020 23:27:05
User entered 'No (N)'	System	09 Sep 2020 23:27:05

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '5a156018-c5c9-4ccc-a977-abe21513013a'	System	09 Sep 2020 23:27:05
User entered '09 Sep 2020 19:27'	System	09 Sep 2020 23:27:05

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 3'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:20:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '60881ed9-64d2-41da-ac05-0320ab2b1696'	System	10 Sep 2020 23:21:01
User entered 'Yes (Y)'	System	10 Sep 2020 23:21:01

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:20:47', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '60881ed9-64d2-41da-ac05-0320ab2b1696'	System	10 Sep 2020 23:21:01
User entered '97.9'	System	10 Sep 2020 23:21:01

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:20:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '60881ed9-64d2-41da-ac05-0320ab2b1696'	System	10 Sep 2020 23:21:01
User entered 'No (N)'	System	10 Sep 2020 23:21:01

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:20:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '60881ed9-64d2-41da-ac05-0320ab2b1696'	System	10 Sep 2020 23:21:01
User entered '10 Sep 2020 19:20'	System	10 Sep 2020 23:21:01

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 4'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd203efc0-3ece-4181-bd14-fd097c5f42e9'	System	11 Sep 2020 23:38:33
User entered 'Yes (Y)'	System	11 Sep 2020 23:38:33

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:21', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd203efc0-3ece-4181-bd14-fd097c5f42e9'	System	11 Sep 2020 23:38:33
User entered '97.5'	System	11 Sep 2020 23:38:33

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:24', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd203efc0-3ece-4181-bd14-fd097c5f42e9'	System	11 Sep 2020 23:38:33
User entered 'No (N)'	System	11 Sep 2020 23:38:33

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:28', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd203efc0-3ece-4181-bd14-fd097c5f42e9'	System	11 Sep 2020 23:38:33
User entered '11 Sep 2020 19:38'	System	11 Sep 2020 23:38:33

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 5'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:17:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7acb844-a377-4b90-a1a3-ad6bb59988af' User entered 'Yes (Y)'	System	12 Sep 2020 23:19:07
	System	12 Sep 2020 23:19:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:18:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7acb844-a377-4b90-a1a3-ad6bb59988af'	System	12 Sep 2020 23:19:07
User entered '97.7'	System	12 Sep 2020 23:19:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:18:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7acb844-a377-4b90-a1a3-ad6bb59988af'	System	12 Sep 2020 23:19:07
User entered 'No (N)'	System	12 Sep 2020 23:19:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:03', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f7acb844-a377-4b90-a1a3-ad6bb59988af'	System	12 Sep 2020 23:19:07
User entered '12 Sep 2020 19:19'	System	12 Sep 2020 23:19:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 6'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:41:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8245fdab-116d-497f-b066-b0964c32b6d6'	System	13 Sep 2020 23:42:07
User entered 'Yes (Y)'	System	13 Sep 2020 23:42:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:41:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8245fdab-116d-497f-b066-b0964c32b6d6'	System	13 Sep 2020 23:42:07
User entered '97.7'	System	13 Sep 2020 23:42:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:41:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8245fdab-116d-497f-b066-b0964c32b6d6'	System	13 Sep 2020 23:42:07
User entered 'No (N)'	System	13 Sep 2020 23:42:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:03', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '8245fdab-116d-497f-b066-b0964c32b6d6'	System	13 Sep 2020 23:42:07
User entered '13 Sep 2020 19:42'	System	13 Sep 2020 23:42:07

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 7'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:41:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc4c72c8-2498-4ddc-a231-8f4ecdf4c032'	System	15 Sep 2020 00:42:11
User entered 'Yes (Y)'	System	15 Sep 2020 00:42:11

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:41:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc4c72c8-2498-4ddc-a231-8f4ecdf4c032'	System	15 Sep 2020 00:42:11
User entered '97.0'	System	15 Sep 2020 00:42:11

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc4c72c8-2498-4ddc-a231-8f4ecdf4c032'	System	15 Sep 2020 00:42:11
User entered 'No (N)'	System	15 Sep 2020 00:42:11

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:08', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bc4c72c8-2498-4ddc-a231-8f4ecdf4c032'	System	15 Sep 2020 00:42:11
User entered '14 Sep 2020 20:42'	System	15 Sep 2020 00:42:11

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:02:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered 'None (1)'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:02:49', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered 'Yes (Y)'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:02:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered '4'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered 'No (N)'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered 'None (1)'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:30', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd0c60876-f203-427b-bd3a-0cb8686b41cf'	System	08 Sep 2020 14:03:36
User entered '08 Sep 2020 10:03'	System	08 Sep 2020 14:03:36

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 09:45'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 12:15'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:21:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '90bbb711-1cb8-4673-a235-9bc66a898b90'	System	08 Sep 2020 23:22:45
User entered 'None (1)'	System	08 Sep 2020 23:22:45

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:03', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '90bbb711-1cb8-4673-a235-9bc66a898b90'	System	08 Sep 2020 23:22:45
User entered 'No (N)'	System	08 Sep 2020 23:22:45

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '90bbb711-1cb8-4673-a235-9bc66a898b90'	System	08 Sep 2020 23:22:45
User entered 'No (N)'	System	08 Sep 2020 23:22:45

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '90bbb711-1cb8-4673-a235-9bc66a898b90'	System	08 Sep 2020 23:22:45
User entered 'None (1)'	System	08 Sep 2020 23:22:45

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '90bbb711-1cb8-4673-a235-9bc66a898b90'	System	08 Sep 2020 23:22:45
User entered '08 Sep 2020 19:22'	System	08 Sep 2020 23:22:45

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 13:10'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 2'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4149c0ef-7391-4d8d-a5d9-e83073c03dc2'	System	09 Sep 2020 23:27:34
User entered 'None (1)'	System	09 Sep 2020 23:27:34

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4149c0ef-7391-4d8d-a5d9-e83073c03dc2'	System	09 Sep 2020 23:27:34
User entered 'No (N)'	System	09 Sep 2020 23:27:34

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4149c0ef-7391-4d8d-a5d9-e83073c03dc2'	System	09 Sep 2020 23:27:34
User entered 'No (N)'	System	09 Sep 2020 23:27:34

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4149c0ef-7391-4d8d-a5d9-e83073c03dc2'	System	09 Sep 2020 23:27:34
User entered 'None (1)'	System	09 Sep 2020 23:27:34

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:31', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4149c0ef-7391-4d8d-a5d9-e83073c03dc2'	System	09 Sep 2020 23:27:34
User entered '09 Sep 2020 19:27'	System	09 Sep 2020 23:27:34

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 3'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:21:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '95205e4f-2746-4156-b959-5cdd0f9c4785'	System	10 Sep 2020 23:22:06
User entered 'None (1)'	System	10 Sep 2020 23:22:06

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:21:29', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '95205e4f-2746-4156-b959-5cdd0f9c4785'	System	10 Sep 2020 23:22:06
User entered 'No (N)'	System	10 Sep 2020 23:22:06

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:21:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '95205e4f-2746-4156-b959-5cdd0f9c4785'	System	10 Sep 2020 23:22:06
User entered 'No (N)'	System	10 Sep 2020 23:22:06

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:21:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '95205e4f-2746-4156-b959-5cdd0f9c4785'	System	10 Sep 2020 23:22:06
User entered 'None (1)'	System	10 Sep 2020 23:22:06

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '95205e4f-2746-4156-b959-5cdd0f9c4785'	System	10 Sep 2020 23:22:06
User entered '10 Sep 2020 19:22'	System	10 Sep 2020 23:22:06

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 4'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:38', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3d0c922c-8b04-4de4-966b-9c6a1fd343cb'	System	11 Sep 2020 23:39:00
User entered 'None (1)'	System	11 Sep 2020 23:39:00

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3d0c922c-8b04-4de4-966b-9c6a1fd343cb'	System	11 Sep 2020 23:39:00
User entered 'No (N)'	System	11 Sep 2020 23:39:00

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3d0c922c-8b04-4de4-966b-9c6a1fd343cb'	System	11 Sep 2020 23:39:00
User entered 'No (N)'	System	11 Sep 2020 23:39:00

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3d0c922c-8b04-4de4-966b-9c6a1fd343cb'	System	11 Sep 2020 23:39:00
User entered 'None (1)'	System	11 Sep 2020 23:39:00

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:38:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3d0c922c-8b04-4de4-966b-9c6a1fd343cb'	System	11 Sep 2020 23:39:00
User entered '11 Sep 2020 19:38'	System	11 Sep 2020 23:39:00

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 5'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '35b10f1b-2795-4b6d-b74e-277352808a15'	System	12 Sep 2020 23:19:43
User entered 'None (1)'	System	12 Sep 2020 23:19:43

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '35b10f1b-2795-4b6d-b74e-277352808a15'	System	12 Sep 2020 23:19:43
User entered 'No (N)'	System	12 Sep 2020 23:19:43

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:30', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '35b10f1b-2795-4b6d-b74e-277352808a15'	System	12 Sep 2020 23:19:43
User entered 'No (N)'	System	12 Sep 2020 23:19:43

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '35b10f1b-2795-4b6d-b74e-277352808a15'	System	12 Sep 2020 23:19:43
User entered 'None (1)'	System	12 Sep 2020 23:19:43

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '35b10f1b-2795-4b6d-b74e-277352808a15'	System	12 Sep 2020 23:19:43
User entered '12 Sep 2020 19:19'	System	12 Sep 2020 23:19:43

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 6'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:13', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bf751213-0dc4-4bdd-a01f-0a1bb460f0b1'	System	13 Sep 2020 23:42:40
User entered 'None (1)'	System	13 Sep 2020 23:42:40

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bf751213-0dc4-4bdd-a01f-0a1bb460f0b1'	System	13 Sep 2020 23:42:40
User entered 'No (N)'	System	13 Sep 2020 23:42:40

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bf751213-0dc4-4bdd-a01f-0a1bb460f0b1'	System	13 Sep 2020 23:42:40
User entered 'No (N)'	System	13 Sep 2020 23:42:40

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:27', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bf751213-0dc4-4bdd-a01f-0a1bb460f0b1'	System	13 Sep 2020 23:42:40
User entered 'None (1)'	System	13 Sep 2020 23:42:40

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:34', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bf751213-0dc4-4bdd-a01f-0a1bb460f0b1'	System	13 Sep 2020 23:42:40
User entered '13 Sep 2020 19:42'	System	13 Sep 2020 23:42:40

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 7'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'dc6e1e79-69f0-4853-b8ea-495725757ee7'	System	15 Sep 2020 00:42:37
User entered 'None (1)'	System	15 Sep 2020 00:42:37

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:17', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'dc6e1e79-69f0-4853-b8ea-495725757ee7'	System	15 Sep 2020 00:42:37
User entered 'No (N)'	System	15 Sep 2020 00:42:37

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'dc6e1e79-69f0-4853-b8ea-495725757ee7'	System	15 Sep 2020 00:42:37
User entered 'No (N)'	System	15 Sep 2020 00:42:37

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:27', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'dc6e1e79-69f0-4853-b8ea-495725757ee7'	System	15 Sep 2020 00:42:37
User entered 'None (1)'	System	15 Sep 2020 00:42:37

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'dc6e1e79-69f0-4853-b8ea-495725757ee7'	System	15 Sep 2020 00:42:37
User entered '14 Sep 2020 20:42'	System	15 Sep 2020 00:42:37

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:38', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:03:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'None (0)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:04:03', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered 'No (N)'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T10:04:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c94c3c4e-ea62-41df-bd64-23e91f978c4b'	System	08 Sep 2020 14:04:42
User entered '08 Sep 2020 10:04'	System	08 Sep 2020 14:04:42

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 09:45'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 12:15'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:49', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:22:59', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:23:01', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'None (0)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:23:05', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered 'No (N)'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-08T19:23:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '2e928ed1-a46f-474d-9ed6-c8a3985eebd4'	System	08 Sep 2020 23:23:20
User entered '08 Sep 2020 19:23'	System	08 Sep 2020 23:23:20

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '08 Sep 2020 13:10'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 2'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:36', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:42', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:27:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'None (0)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:28:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered 'Yes (Y)'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-09T19:28:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '3661f319-b91c-4247-a545-331e791b08f3'	System	09 Sep 2020 23:28:09
User entered '09 Sep 2020 19:28'	System	09 Sep 2020 23:28:09

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 3'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:05', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:11', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:13', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:15', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'None (0)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:18', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered 'No (N)'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-10T19:22:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b7ec335-b2cd-49da-ad37-e7ada38483b8'	System	10 Sep 2020 23:22:28
User entered '10 Sep 2020 19:22'	System	10 Sep 2020 23:22:28

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 4'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:04', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:06', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:08', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'None (0)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered 'No (N)'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-11T19:39:23', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6a4e1555-22f6-4586-8b9b-29a21b4f8707'	System	11 Sep 2020 23:39:26
User entered '11 Sep 2020 19:39'	System	11 Sep 2020 23:39:26

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 5'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:47', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:49', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'None (0)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:19:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered 'No (N)'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-12T19:20:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '972fa79e-f865-4847-b280-1cf2b58d3e1f'	System	12 Sep 2020 23:20:16
User entered '12 Sep 2020 19:20'	System	12 Sep 2020 23:20:16

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 6'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:48', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'None (0)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:42:55', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered 'No (N)'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-13T19:43:02', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9a13bbbb-dbd0-4257-8e0d-e4b3613b1732'	System	13 Sep 2020 23:43:07
User entered '13 Sep 2020 19:43'	System	13 Sep 2020 23:43:07

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	08 Sep 2020 13:32:41
User entered 'Day 7'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:38', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:42', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:46', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'None (0)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered 'No (N)'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-09-14T20:42:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'bdd68149-db29-4a7c-adf4-f20940c46349'	System	15 Sep 2020 00:43:04
User entered '14 Sep 2020 20:42'	System	15 Sep 2020 00:43:04

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:32:41

US3412208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:32:41

US3412208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:14

US3412208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:14

US3412208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:14

US3412208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:14

US3412208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:57:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:21

US3412208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	15 Sep 2020 13:53:21

US3412208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 14:34:45

US3412208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '22 Sep 2020'	Mason Urban (b) (4)	22 Sep 2020 14:34:45

US3412208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Sep 2020 14:34:45

US3412208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Mason Urban (b) (4)	22 Sep 2020 14:34:45

US3412208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 14:34:50

US3412208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	22 Sep 2020 14:34:50

US3412208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Sep 2020 15:09:53

US3412208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '29 Sep 2020'	Mason Urban (b) (4)	29 Sep 2020 15:09:53

US3412208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Sep 2020 15:09:53

US3412208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Mason Urban (b) (4)	29 Sep 2020 15:09:53

US3412208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Sep 2020 15:09:58

US3412208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	29 Sep 2020 15:09:58

US3412208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 12:19:40

US3412208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 12:19:40

US3412208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	06 Oct 2020 12:19:40

US3412208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'VISIT3'	System	06 Oct 2020 12:19:40

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'No (N)'	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered empty.	System	06 Oct 2020 12:19:53

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24

US3412208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24

US3412208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 12:20:03

US3412208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 12:20:03

US3412208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 12:20:27

US3412208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 12:20:27

US3412208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered '08:02'	Steven Anderson (b) (4)	06 Oct 2020 12:20:27

US3412208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '06 Oct 2020 08:02'	System	06 Oct 2020 12:20:27

US3412208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:46:13
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 12:20:31

US3412208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered '1'	System	06 Oct 2020 12:20:31

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 64'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-13T09:01:33', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6facaf03-d60e-4025-9df3-c89236334466'	System	13 Oct 2020 13:02:40
User entered 'No (N)'	System	13 Oct 2020 13:02:40

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you been exposed to someone with 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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-13T09:02:30', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6facaf03-d60e-4025-9df3-c89236334466'	System	13 Oct 2020 13:02:40
User entered 'No (N)'	System	13 Oct 2020 13:02:40

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-13T09:02:35', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6facaf03-d60e-4025-9df3-c89236334466'	System	13 Oct 2020 13:02:40
User entered '13 Oct 2020 09:02:35'	System	13 Oct 2020 13:02:40

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 71'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-20T09:30:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'aeb5ff84-5a50-444e-aef1-0bbe78958317'	System	20 Oct 2020 13:31:10
User entered 'No (N)'	System	20 Oct 2020 13:31:10

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-20T09:30:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'aeb5ff84-5a50-444e-aef1-0bbe78958317'	System	20 Oct 2020 13:31:10
User entered 'No (N)'	System	20 Oct 2020 13:31:10

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-20T09:31:07', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'aeb5ff84-5a50-444e-aef1-0bbe78958317'	System	20 Oct 2020 13:31:10
User entered '20 Oct 2020 09:31:07'	System	20 Oct 2020 13:31:10

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 78'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-27T09:30:39', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f78d75e6-a8d0-48db-a76d-ada77a380c00'	System	27 Oct 2020 13:30:55
User entered 'No (N)'	System	27 Oct 2020 13:30:55

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-27T09:30:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f78d75e6-a8d0-48db-a76d-ada77a380c00'	System	27 Oct 2020 13:30:55
User entered 'No (N)'	System	27 Oct 2020 13:30:55

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-10-27T09:30:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'f78d75e6-a8d0-48db-a76d-ada77a380c00'	System	27 Oct 2020 13:30:55
User entered '27 Oct 2020 09:30:50'	System	27 Oct 2020 13:30:55

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 92'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-10T09:31:09', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7edfff10-4f73-4a33-b07e-fbc2918600ae'	System	10 Nov 2020 14:31:29
User entered 'No (N)'	System	10 Nov 2020 14:31:29

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-10T09:31:18', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7edfff10-4f73-4a33-b07e-fbc2918600ae'	System	10 Nov 2020 14:31:29
User entered 'No (N)'	System	10 Nov 2020 14:31:29

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-10T09:31:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7edfff10-4f73-4a33-b07e-fbc2918600ae'	System	10 Nov 2020 14:31:29
User entered '10 Nov 2020 09:31:25'	System	10 Nov 2020 14:31:29

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered 'Day 99'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-17T09:30:47', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9acb72d7-cb07-45a9-8c0c-31127c93be2e'	System	17 Nov 2020 14:30:57
User entered 'No (N)'	System	17 Nov 2020 14:30:57

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-17T09:30:49', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9acb72d7-cb07-45a9-8c0c-31127c93be2e'	System	17 Nov 2020 14:30:57
User entered 'No (N)'	System	17 Nov 2020 14:30:57

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-11-17T09:30:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9acb72d7-cb07-45a9-8c0c-31127c93be2e'	System	17 Nov 2020 14:30:57
User entered '17 Nov 2020 09:30:53'	System	17 Nov 2020 14:30:57

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 20:46:37

US3412208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:40:36
Data entry locked.	System	11 Aug 2020 20:46:37
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 20:46:37

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2020-12-03T07:55:01', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '06d20e2b-8bf8-4103-b34d-71ff5770108f'	System	03 Dec 2020 12:55:17
User entered 'No (N)'	System	03 Dec 2020 12:55:17

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2020-12-03T07:55:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '06d20e2b-8bf8-4103-b34d-71ff5770108f'	System	03 Dec 2020 12:55:17
User entered 'No (N)'	System	03 Dec 2020 12:55:17

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-03T07:55:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '06d20e2b-8bf8-4103-b34d-71ff5770108f' User entered '03 Dec 2020 07:55:14'	System	03 Dec 2020 12:55:17
	System	03 Dec 2020 12:55:17

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2020-12-10T09:31:10', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'Yes (Y)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2020-12-10T09:31:14', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'Yes (Y)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Please 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 (751a3f768b5598cc)', Time: '2020-12-10T09:31:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:24', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'Yes (Y)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '0'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered '1'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Please 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 (751a3f768b5598cc)', Time: '2020-12-10T09:31:43', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929'	System	10 Dec 2020 14:32:05
User entered 'No (N)'	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-10T09:31:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'b40191cf-95f8-450d-b02f-018decfc9929' User entered '10 Dec 2020 09:31:54'	System	10 Dec 2020 14:32:05
	System	10 Dec 2020 14:32:05

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2020-12-17T09:30:45', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'Yes (Y)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2020-12-17T09:30:50', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'Yes (Y)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Please 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 (751a3f768b5598cc)', Time: '2020-12-17T09:30:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:30:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'Yes (Y)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d' User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '0'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:12', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered '1'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Please 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 (751a3f768b5598cc)', Time: '2020-12-17T09:31:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'Yes (Y)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Please 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 (751a3f768b5598cc)', Time: '2020-12-17T09:31:24', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d'	System	17 Dec 2020 14:31:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-17T09:31:28', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '6120e008-a856-46e3-aa37-8695cec16a2d' User entered '17 Dec 2020 09:31:28'	System	17 Dec 2020 14:31:40
	System	17 Dec 2020 14:31:40

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2020-12-24T09:30:41', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '342c01c2-29df-4859-b4cb-a45144e2368b'	System	24 Dec 2020 14:31:04
User entered 'Yes (Y)'	System	24 Dec 2020 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2020-12-24T09:30:44', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '342c01c2-29df-4859-b4cb-a45144e2368b'	System	24 Dec 2020 14:31:04
User entered 'No (N)'	System	24 Dec 2020 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-24T09:30:47', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '342c01c2-29df-4859-b4cb-a45144e2368b'	System	24 Dec 2020 14:31:04
User entered 'No (N)'	System	24 Dec 2020 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-24T09:30:53', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '342c01c2-29df-4859-b4cb-a45144e2368b'	System	24 Dec 2020 14:31:04
User entered 'No (N)'	System	24 Dec 2020 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2020-12-24T09:30:56', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '342c01c2-29df-4859-b4cb-a45144e2368b'	System	24 Dec 2020 14:31:04
User entered '24 Dec 2020 09:30:56'	System	24 Dec 2020 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-01-07T04:20:25', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a58e7606-2ea3-4d10-b86b-f160286ed21c'	System	07 Jan 2021 09:20:42
User entered 'No (N)'	System	07 Jan 2021 09:20:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-01-07T04:20:28', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a58e7606-2ea3-4d10-b86b-f160286ed21c'	System	07 Jan 2021 09:20:42
User entered 'No (N)'	System	07 Jan 2021 09:20:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-01-07T04:20:35', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a58e7606-2ea3-4d10-b86b-f160286ed21c'	System	07 Jan 2021 09:20:42
User entered '07 Jan 2021 04:20:35'	System	07 Jan 2021 09:20:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-01-14T09:31:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b106ddf-0dd2-4d85-b7c7-d6663518ea21'	System	16 Jan 2021 17:56:42
User entered 'No (N)'	System	16 Jan 2021 17:56:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-01-16T12:56:26', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b106ddf-0dd2-4d85-b7c7-d6663518ea21'	System	16 Jan 2021 17:56:42
User entered 'No (N)'	System	16 Jan 2021 17:56:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-01-16T12:56:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '0b106ddf-0dd2-4d85-b7c7-d6663518ea21'	System	16 Jan 2021 17:56:42
User entered '16 Jan 2021 12:56:37'	System	16 Jan 2021 17:56:42

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-01-21T10:06:47', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7d52ead3-7880-4ddd-80c4-4caf894f11dc'	System	21 Jan 2021 15:07:01
User entered 'No (N)'	System	21 Jan 2021 15:07:01

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-01-21T10:06:52', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7d52ead3-7880-4ddd-80c4-4caf894f11dc'	System	21 Jan 2021 15:07:01
User entered 'No (N)'	System	21 Jan 2021 15:07:01

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-01-21T10:06:57', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7d52ead3-7880-4ddd-80c4-4caf894f11dc' User entered '21 Jan 2021 10:06:57'	System	21 Jan 2021 15:07:01

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-01-28T09:30:30', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd3f5b245-96cb-4999-874c-f3d9ac26e3e5'	System	28 Jan 2021 14:30:41
User entered 'No (N)'	System	28 Jan 2021 14:30:41

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-01-28T09:30:32', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd3f5b245-96cb-4999-874c-f3d9ac26e3e5'	System	28 Jan 2021 14:30:41
User entered 'No (N)'	System	28 Jan 2021 14:30:41

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-01-28T09:30:35', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'd3f5b245-96cb-4999-874c-f3d9ac26e3e5'	System	28 Jan 2021 14:30:41
User entered '28 Jan 2021 09:30:35'	System	28 Jan 2021 14:30:41

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-02-04T09:34:51', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '531867f1-41cd-4d49-b35a-10acd1e516bb'	System	04 Feb 2021 14:35:03
User entered 'No (N)'	System	04 Feb 2021 14:35:03

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-02-04T09:34:54', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '531867f1-41cd-4d49-b35a-10acd1e516bb'	System	04 Feb 2021 14:35:03
User entered 'No (N)'	System	04 Feb 2021 14:35:03

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-02-04T09:34:58', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '531867f1-41cd-4d49-b35a-10acd1e516bb' User entered '04 Feb 2021 09:34:58'	System	04 Feb 2021 14:35:03
	System	04 Feb 2021 14:35:03

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-02-11T09:31:16', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a2a0f573-8443-4195-800f-23123fc5aea9'	System	11 Feb 2021 14:31:28
User entered 'No (N)'	System	11 Feb 2021 14:31:28

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-02-11T09:31:19', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a2a0f573-8443-4195-800f-23123fc5aea9'	System	11 Feb 2021 14:31:28
User entered 'No (N)'	System	11 Feb 2021 14:31:28

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-02-11T09:31:22', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'a2a0f573-8443-4195-800f-23123fc5aea9'	System	11 Feb 2021 14:31:28
User entered '11 Feb 2021 09:31:22'	System	11 Feb 2021 14:31:28

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-02-18T09:30:34', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'ec8b7e65-296a-4c22-a9aa-445a8c11bd7f'	System	18 Feb 2021 14:30:47
User entered 'No (N)'	System	18 Feb 2021 14:30:47

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-02-18T09:30:37', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'ec8b7e65-296a-4c22-a9aa-445a8c11bd7f'	System	18 Feb 2021 14:30:47
User entered 'No (N)'	System	18 Feb 2021 14:30:47

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-02-18T09:30:40', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'ec8b7e65-296a-4c22-a9aa-445a8c11bd7f'	System	18 Feb 2021 14:30:47
User entered '18 Feb 2021 09:30:40'	System	18 Feb 2021 14:30:47

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-02-25T09:30:35-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7ff69e53-7183-49a1-9306-7dad2977ccc6'	System	25 Feb 2021 14:30:49
User entered 'No (N)'	System	25 Feb 2021 14:30:49

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-02-25T09:30:38-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7ff69e53-7183-49a1-9306-7dad2977ccc6'	System	25 Feb 2021 14:30:49
User entered 'No (N)'	System	25 Feb 2021 14:30:49

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-02-25T09:30:42-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '7ff69e53-7183-49a1-9306-7dad2977ccc6'	System	25 Feb 2021 14:30:49
User entered '25 Feb 2021 09:30:42'	System	25 Feb 2021 14:30:49

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-03-11T09:30:53-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9156f8b4-917a-4679-9e3c-1978e71ef60a' User entered 'No (N)'	System	11 Mar 2021 14:31:04
	System	11 Mar 2021 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-03-11T09:30:56-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9156f8b4-917a-4679-9e3c-1978e71ef60a' User entered 'No (N)'	System	11 Mar 2021 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-03-11T09:31:00-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '9156f8b4-917a-4679-9e3c-1978e71ef60a'	System	11 Mar 2021 14:31:04
User entered '11 Mar 2021 09:31:00'	System	11 Mar 2021 14:31:04

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-03-18T09:31:47-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1876209a-87e1-4b9b-8552-35f8b629ca8c'	System	18 Mar 2021 13:31:56
User entered 'No (N)'	System	18 Mar 2021 13:31:56

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-03-18T09:31:49-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1876209a-87e1-4b9b-8552-35f8b629ca8c'	System	18 Mar 2021 13:31:56
User entered 'No (N)'	System	18 Mar 2021 13:31:56

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-03-18T09:31:52-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1876209a-87e1-4b9b-8552-35f8b629ca8c'	System	18 Mar 2021 13:31:56
User entered '18 Mar 2021 09:31:52'	System	18 Mar 2021 13:31:56

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-03-25T09:30:59-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fe08c1ae-6272-4e4f-998e-60278efb4176'	System	25 Mar 2021 13:31:10
User entered 'No (N)'	System	25 Mar 2021 13:31:10

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-03-25T09:31:02-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fe08c1ae-6272-4e4f-998e-60278efb4176'	System	25 Mar 2021 13:31:10
User entered 'No (N)'	System	25 Mar 2021 13:31:10

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-03-25T09:31:05-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'fe08c1ae-6272-4e4f-998e-60278efb4176' User entered '25 Mar 2021 09:31:05'	System	25 Mar 2021 13:31:10
	System	25 Mar 2021 13:31:10

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-04-01T09:47:38-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'e17b77c9-76ff-4857-95c4-afef71006674' User entered 'No (N)'	System	01 Apr 2021 13:47:52
	System	01 Apr 2021 13:47:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-04-01T09:47:40-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'e17b77c9-76ff-4857-95c4-afef71006674'	System	01 Apr 2021 13:47:52
User entered 'No (N)'	System	01 Apr 2021 13:47:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-04-01T09:47:44-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'e17b77c9-76ff-4857-95c4-afef71006674'	System	01 Apr 2021 13:47:52
User entered '01 Apr 2021 09:47:44'	System	01 Apr 2021 13:47:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-04-08T09:30:58-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b70d475-1b0b-41eb-8b3f-c8abdc52d5c8'	System	08 Apr 2021 13:31:11
User entered 'No (N)'	System	08 Apr 2021 13:31:11

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-04-08T09:31:01-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b70d475-1b0b-41eb-8b3f-c8abdc52d5c8'	System	08 Apr 2021 13:31:11
User entered 'No (N)'	System	08 Apr 2021 13:31:11

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-04-08T09:31:05-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b70d475-1b0b-41eb-8b3f-c8abdc52d5c8'	System	08 Apr 2021 13:31:11
User entered '08 Apr 2021 09:31:05'	System	08 Apr 2021 13:31:11

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-04-15T09:43:42-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4904de0e-2bdd-4420-9c25-b79db5f57825'	System	15 Apr 2021 13:45:31
User entered 'No (N)'	System	15 Apr 2021 13:45:31

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-04-15T09:43:45-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4904de0e-2bdd-4420-9c25-b79db5f57825'	System	15 Apr 2021 13:45:31
User entered 'No (N)'	System	15 Apr 2021 13:45:31

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-04-15T09:43:49-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '4904de0e-2bdd-4420-9c25-b79db5f57825'	System	15 Apr 2021 13:45:31
User entered '15 Apr 2021 09:43:49'	System	15 Apr 2021 13:45:31

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-04-22T09:30:43-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b682129-bca2-4e23-a57b-cccfe7856a5c'	System	22 Apr 2021 13:30:52
User entered 'No (N)'	System	22 Apr 2021 13:30:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-04-22T09:30:46-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b682129-bca2-4e23-a57b-cccfe7856a5c'	System	22 Apr 2021 13:30:52
User entered 'No (N)'	System	22 Apr 2021 13:30:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-04-22T09:30:49-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '1b682129-bca2-4e23-a57b-cccfe7856a5c'	System	22 Apr 2021 13:30:52
User entered '22 Apr 2021 09:30:49'	System	22 Apr 2021 13:30:52

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[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 (751a3f768b5598cc)', Time: '2021-04-29T09:32:24-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c8d911ce-ebbe-4b6c-8750-1df591147a42'	System	29 Apr 2021 13:32:53
User entered 'No (N)'	System	29 Apr 2021 13:32:53

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

Have you been exposed to someone with 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 (751a3f768b5598cc)', Time: '2021-04-29T09:32:26-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c8d911ce-ebbe-4b6c-8750-1df591147a42'	System	29 Apr 2021 13:32:53
User entered 'No (N)'	System	29 Apr 2021 13:32:53

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-04-29T09:32:30-04:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: 'c8d911ce-ebbe-4b6c-8750-1df591147a42'	System	29 Apr 2021 13:32:53
User entered '29 Apr 2021 09:32:30'	System	29 Apr 2021 13:32:53

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:10:55

US3412208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:55
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:10:55

US3412208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:06

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)	26 Apr 2021 00:35:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-03-11T09:30:39-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '87fb53cb-88b0-4e89-a4c9-e963a0912db4'	System	11 Mar 2021 14:30:50
User entered 'No (N)'	System	11 Mar 2021 14:30:50

US3412208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:35:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (751a3f768b5598cc)', Time: '2021-03-11T09:30:47-05:00', User OID: 'PatientReportedOutcome (US3412208)', ODM File OID: '87fb53cb-88b0-4e89-a4c9-e963a0912db4' User entered '11 Mar 2021 09:30:47'	System	11 Mar 2021 14:30:50
	System	11 Mar 2021 14:30:50

US3412208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Nov 2020 18:50:14

US3412208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered '3 Nov 2020'	Mason Urban (b) (4)	03 Nov 2020 18:50:14

US3412208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	03 Nov 2020 18:50:14

US3412208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered empty.	Mason Urban (b) (4)	03 Nov 2020 18:50:14

US3412208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Nov 2020 18:50:19

US3412208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:09:24
User entered 'I'	System	03 Nov 2020 18:50:19

US3412208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Dec 2020 17:29:02

US3412208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Dec 2020'	Mason Urban (b) (4)	08 Dec 2020 17:29:02

US3412208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Dec 2020 17:29:02

US3412208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	08 Dec 2020 17:29:02

US3412208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Dec 2020 17:28:50

US3412208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User entered 'I'	System	08 Dec 2020 17:28:50

US3412208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 18:15:46

US3412208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 18:15:46

US3412208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	06 Jan 2021 18:15:46

US3412208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 18:15:46

US3412208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 18:15:58

US3412208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User entered 'I'	System	06 Jan 2021 18:15:58

US3412208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Feb 2021 17:52:50

US3412208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '5 Feb 2021'	Mason Urban (b) (4)	11 Feb 2021 17:52:50

US3412208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	11 Feb 2021 17:52:50

US3412208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	11 Feb 2021 17:52:50

US3412208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Feb 2021 17:52:56

US3412208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:13
User entered 'I'	System	11 Feb 2021 17:52:56

US3412208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:03

US3412208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:03

US3412208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[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 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:03

US3412208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'VISIT4'	System	04 Mar 2021 14:57:03

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '08:16'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '04 Mar 2021 08:16'	System	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '36.6' C	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '98'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'bpm'	System	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '14'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'breaths/min'	System	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '120'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'mmHg'	System	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '70'	Andrea Newlands (b) (4)	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'mmHg'	System	30 Mar 2021 19:34:01

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50

US3412208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50

US3412208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:09

US3412208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:57:09

US3412208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:21

US3412208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:21

US3412208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '08:34'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:21

US3412208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered '04 Mar 2021 08:34'	System	04 Mar 2021 14:57:21

US3412208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:57:25

US3412208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:30:50
User entered 'I'	System	04 Mar 2021 14:57:25

US3412208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:55:29

US3412208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:55:29

US3412208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:55:29

US3412208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:55:29

US3412208

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 19:55:31

US3412208

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 19:55:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:06

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 07:28:43
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' answered with 'SAMPLE WAS SHIPPED ON ACCESSION NUMBER 1F65955' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:25:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:36:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:22:12
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:34:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:06

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Please confirm time of contact' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:04:29
DataPoint Verified.		27 Jan 2021 14:04:27
Query 'Please confirm time of contact' answered with 'UPDATED TIME OF CONTACT' (Site from CRA).	Melissa Fuson (b) (4)	16 Dec 2020 13:25:36
User entered '12:35' reason for change: Data Entry Error	Melissa Fuson (b) (4)	16 Dec 2020 13:25:19
User opened query 'Please confirm time of contact' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 22:22:34
DataPoint Un-verified.		15 Dec 2020 22:22:22
DataPoint Verified.		15 Dec 2020 22:22:12
User entered '12:40'	Melissa Fuson (b) (4)	10 Dec 2020 20:34:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:06

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:12
User entered '10 Dec 2020 12:35'	System	16 Dec 2020 13:25:19
User entered '10 Dec 2020 12:40'	System	10 Dec 2020 20:34:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:06

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:22:12
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:34:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:06

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:22:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:34:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered '6 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Please complete with symptom information for this day per contact page in source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:17:57
DataPoint Verified.		11 Feb 2021 18:17:41
Query 'Please complete with symptom information for this day per contact page in source' answered with 'symptoms have been updated per contact page.' (Site from CRA).	Steven Anderson (b) (4)	27 Jan 2021 20:21:43
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User opened query 'Please complete with symptom information for this day per contact page in source' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:06:43
User entered '1'	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	27 Jan 2021 20:21:10
User entered empty.	System	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:06
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:16:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:17:41
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:21:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:21

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '7 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered '1'	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	27 Jan 2021 20:24:33
User entered empty.	System	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:33
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:36:46

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:24:58
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:36:46

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '8 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered '1'	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 20:26:42
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	27 Jan 2021 20:26:42
User entered empty.	System	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:26:42
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:27:08
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:37:54

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '9 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered '1' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 14:42:11
User entered '0'	(b) (4) Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User closed query 'Per CDM: It appears that values for Day 4 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:46:50
Query 'Per CDM: It appears that values for Day 4 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'THIS SHOULD HAVE BEEN MARKED ASSESSMENT NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 14:43:50
User opened query 'Per CDM: It appears that values for Day 4 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 11:13:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	27 Jan 2021 20:29:16
User entered empty.	System	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:19:33
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:29:41
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:38:09

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 5 (Day 5)'	Melissa Fuson (b) (4)	10 Dec 2020 20:40:07

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:18
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Per ETRTR: Please add O2 saturation at Illness Visit Day 1. If not completed ensure stating so, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:21:41
DataPoint Verified.		27 Jan 2021 14:21:39
Query 'Per ETRTR: Please add O2 saturation at Illness Visit Day 1. If not completed ensure stating so, thanks.' answered with 'O2 SATURATION NOT DONE' (Site from CRA).	Melissa Fuson (b) (4)	22 Dec 2020 13:08:19
DataPoint Un-verified.	(b) (4)	
	Melissa Fuson (b) (4)	22 Dec 2020 13:07:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	22 Dec 2020 13:07:06
User opened query 'Per ETRTR: Please add O2 saturation at Illness Visit Day 1. If not completed ensure stating so, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:23:09
DataPoint Verified.		15 Dec 2020 22:27:22
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 20:40:07
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	22 Dec 2020 13:07:06
User entered empty.	System	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:25
User entered '37.0' C	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:27
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:30
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:33
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:36
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:38
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:39
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:44
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:45
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:51
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:52
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:55
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:28:57
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:29:01
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:29:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:40:07

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:22:52
User entered '11 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:22:54
User entered '0'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:22:57
User entered '94'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:22:59
User entered '97.8' F	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:14
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:22
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:24
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:35
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:37
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:39
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:45
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:47
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:54
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:58
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:24:01
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:38:50

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 7 (Day 7)'	Melissa Fuson (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:16
User entered '12 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:19
User entered '0'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:30
User entered '96'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:32
User entered '97.6' F	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:48
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:25:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:01
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:06
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:10
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:23
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:30
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:26:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:00:22

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 8 (Day 8)'	Melissa Fuson (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:30:03
User entered '13 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:30:05
User entered '0'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:30:49
User entered '90'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:30:53
User entered '97.6' F	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:00
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:02
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:06
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:10
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:14
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:23
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:35
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:43
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:31:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:02:20

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	15 Dec 2020 14:04:24
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	15 Dec 2020 14:04:06
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:27
User entered '14 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:29
User entered '0'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:33
User entered '96'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:36
User entered '98.6' F	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:52
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:56
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:33:58
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:11
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:13
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:15
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:34:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 14:04:06

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 10 (Day 10)'	Melissa Fuson (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:03
User entered '15 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:04
User entered '0'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:07
User entered '95'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:12
User entered '97.9' F	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:15
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:27
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:30
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:32
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:36
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:42
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:44
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:35:48
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:11
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:14
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:37:48

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	16 Dec 2020 19:00:53
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	16 Dec 2020 18:59:18
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:57
User entered '16 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:36:59
User entered '0'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:33
User entered '93'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:35
User entered '98.6' F	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:55
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:37:57
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:09
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:11
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:23
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:38:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 18:59:18

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 12 (Day 12)'	Melissa Fuson (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:05
User entered '17 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:07
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:12
User entered '96'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:13
User entered '98.6' F	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:32
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:37
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:38
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:43
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:45
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:46
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:50
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:57
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:39:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:40:01
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:40:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:28:32

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:41:19
User entered '18 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:41:20
User entered '0'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:07
User entered '97'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:09
User entered '97.9' F	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:15
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:24
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:52
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:41
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:43
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:42:57
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:43:06
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:43:08
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:43:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:43:12
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Dec 2020 17:30:31

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 14 (Day 14)'	Melissa Fuson (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:11
User entered '19 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:13
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:16
User entered '97'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:18
User entered '97.6' F	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:24
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:29
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:35
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:36
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:38
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:44:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:29
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:35
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:37
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:25:39

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 15 (Day 15)'	Melissa Fuson (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:21
User entered '20 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:22
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:28
User entered '97'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Dec 2020 13:35:19
User entered '98.9' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:35:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Dec 2020 13:30:27
User entered '98..9' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:45
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:46:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:01
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:08
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:14
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:16
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:30:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 16 (Day 16)'	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:44
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 13:33:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 13:33:15
User entered '21 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:33:15
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 13:31:43
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:46
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:50
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	22 Dec 2020 13:33:15
User entered empty.	System	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:47:52
User entered '97.7' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:04
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:05
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:07
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:15
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:17
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:18
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:20
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:22
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:23
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:25
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:27
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:28
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:30
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:32
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 13:33:15
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 13:31:43

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 17 (Day 17)'	Melissa Fuson (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:10
User entered '22 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:11
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:18
User entered '97'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:19
User entered '97.4' F	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:50
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:53
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:49:57
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:01:10

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:04:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	30 Dec 2020 14:04:27
	(b) (4)	

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:50:29
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:50:30
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:50:32
User entered '97'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User entered '%'	System	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:50:33
User entered '97.6' F	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:00
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:09
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:14
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:16
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:23
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:43:06

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:51:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:04:27

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:40
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:42
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:43
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).		18 Dec 2020 13:40:16
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 'UPDATED TO YES AND LEFT QUERY FOR SUB I TO CHANGE NAME ON AE LOG AND AE EDC' (Site from System).	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 18:53:24
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 13:45:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 13:45:58
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	15 Dec 2020 13:45:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:45:58
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 20:35:12
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:46
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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).		18 Dec 2020 07:28:48
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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 WAS SHIPPED. ACCESSION NUMBER: 1F65955' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:19:21
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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)	16 Dec 2020 05:38:26
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[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)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:53
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:56
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:03:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:12

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Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:06

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:30
User entered 'I'	System	15 Dec 2020 13:45:58

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:05:23
DataPoint Un-verified.		27 Jan 2021 15:04:50
DataPoint Verified.		27 Jan 2021 15:04:29
User entered '13 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:22:16
User closed query 'Please update to end date of 16 Dec 2020 since subject had SpO2 of 93% on this date' (Site from CRA).		11 Feb 2021 18:22:14
Query 'Please update to end date of 16 Dec 2020 since subject had SpO2 of 93% on this date' answered with 'updated spo2 date to 16-dec-2020' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:44:10
User entered '16 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:43:52
User opened query 'Please update to end date of 16 Dec 2020 since subject had SpO2 of 93% on this date' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:06:00
DataPoint Un-verified.		27 Jan 2021 15:04:48
DataPoint Verified.		27 Jan 2021 15:04:29
User entered '13 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered '90'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:54:12
User closed query 'Per CDM re-query: Response to 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' has been removed, however this is a required question. Please provide response.' (Site from DM).		10 Feb 2021 13:39:49
Query 'Per CDM re-query: Response to 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' has been removed, however this is a required question. Please provide response.' answered with 'updated with no' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:45:18
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:45:08
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:44:48
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:43:52
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:43:52
User opened query 'Per CDM re-query: Response to 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' has been removed, however this is a required question. Please provide response.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 16:13:53
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' (Site from DM).		03 Feb 2021 16:13:53
User closed query 'Data is required. Please complete.' (Site from System).		03 Feb 2021 16:12:30
DataPoint Verified.		27 Jan 2021 15:04:29

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'WAS ENTERED IN ERROR' (Site from System).	Melissa Fuson (b) (4)	19 Jan 2021 17:41:22
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' answered with 'WAS DATA ENTRY ERROR' (Site from DM).	Melissa Fuson (b) (4)	19 Jan 2021 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 17:40:42
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	19 Jan 2021 17:40:42
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are recorded as NO yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:18:14
User entered 'No (N)'	Melissa Fuson (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:22:39
User closed query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).		10 Feb 2021 13:40:24
Query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' answered with 'updated and left blank' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:45:36
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:43:52
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Feb 2021 20:43:52
User opened query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 16:15:25
DataPoint Verified.		27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:52:07
User closed query 'please delete No and leave blank' (Site from CRA).		02 Mar 2021 16:52:05
User closed query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).		24 Feb 2021 08:59:02
Query 'please delete No and leave blank' answered with 'updated' (Site from CRA).		
Query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	23 Feb 2021 20:12:26
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	23 Feb 2021 20:12:20
	(b) (4)	
User opened query 'please delete No and leave blank' (Site from CRA).	Andrea Newlands (b) (4)	23 Feb 2021 20:12:09
User opened query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:28:36
		11 Feb 2021 18:27:49
		10 Feb 2021 13:40:45
		27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4)	15 Dec 2020 13:54:30
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

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Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:52:12
User closed query 'please delete No and leave blank' (Site from CRA).		02 Mar 2021 16:52:11
User closed query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).		24 Feb 2021 08:59:09
Query 'please delete No and leave blank' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	23 Feb 2021 20:12:39
Query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4) Andrea Newlands (b) (4)	23 Feb 2021 20:12:35
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	23 Feb 2021 20:12:30
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:28:31
User opened query 'please delete No and leave blank' (Site from CRA).		11 Feb 2021 18:28:01
User opened query 'Per CDM: If responses to 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are both NO, this section is not required and so should be left blank. Please review and update as appropriate.' (Site from DM).		10 Feb 2021 13:40:52
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:06

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:04:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 13:54:30

US3412208

Folder: Covid-19 Assessment 10 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:43:06

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:06:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:07:19
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:35:27

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Thank you for the response, please kindly amend the correct sample collection date in Preclarus as well, and update in the response once it is corrected.Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 04:57:27
Query 'Per GCL Lab Reconciliation: Saliva: Thank you for the response, please kindly amend the correct sample collection date in Preclarus as well, and update in the response once it is corrected.Thank you.' answered with 'information has been updated. called PPD 09APR2021' (Site from DM).		09 Apr 2021 15:34:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Thank you for the response, please kindly amend the correct sample collection date in Preclarus as well, and update in the response once it is corrected.Thank you.' (Site from DM).		10 Feb 2021 13:47:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Day 3 collected date is 12DEC2020 or 15DEC2020.Thanks' (Site from DM).		10 Feb 2021 13:47:11
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Day 3 collected date is 12DEC2020 or 15DEC2020.Thanks' answered with 'subject collected their saliva on 12-Dec-2020' (Site from DM).	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 20:01:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if Day 3 collected date is 12DEC2020 or 15DEC2020.Thanks' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 04:35:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however 15DEC2020 is reported under Illness Visits Day 3 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).		22 Jan 2021 04:35:51

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however 15DEC2020 is reported under Illness Visits Day 3 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' answered with 'DAYS 3,5,7,9 WERE ALL SENT AT SAME TIME ON ACCESSION NUMBER 1F65955' (Site from DM).	Melissa Fuson (b) (4)	19 Jan 2021 17:23:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however 15DEC2020 is reported under Illness Visits Day 3 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:35:28
User accepted default value 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:22:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however the 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).		31 Dec 2020 09:34:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however the 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 'PER ACCESSION NUMBER: 1F65955 SAMPLE WAS SENT AND RECEIVED BY GCL LAB' (Site from DM).	Melissa Fuson (b) (4)	30 Dec 2020 13:56:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness Visit Day 3 in EDC, however the 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 07:21:58
User entered '12 Dec 2020'	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered '14 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 14:25:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 14:25:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:25:32
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 14:22:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:22:50
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15,18DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		31 Dec 2020 09:36:11
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15,18DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'SAMPLE WAS COLLECTED AND EDC WAS UPDATED' (Site from DM).	Melissa Fuson (b) (4)	30 Dec 2020 14:16:08
User entered '16 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:15:51
User entered '15 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:13:44
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15,18DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:38:17
User entered '16 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	18 Dec 2020 15:28:01
User entered empty.	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Per ETRTR: Please confirm whether Saliva Collection was completed for Day 9 and onwards. If not done, please consider deviation reporting as applicable, thanks.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:23:02
		27 Jan 2021 16:22:50
Query 'Per ETRTR: Please confirm whether Saliva Collection was completed for Day 9 and onwards. If not done, please consider deviation reporting as applicable, thanks.' answered with 'WAS COMPLETED AND SENT PER ACCESSION NUMBER 1F65955' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:11:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:10:24
User opened query 'Per ETRTR: Please confirm whether Saliva Collection was completed for Day 9 and onwards. If not done, please consider deviation reporting as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 00:22:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 19:02:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 19:02:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 19:02:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 14:22:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered '18 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:16:52
User entered '15 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:10:24
User entered empty.	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:27:56
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Dec 2020 14:19:37
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 19:02:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 19:02:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 19:02:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 14:22:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered '23 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Jan 2021 17:27:56
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	11 Feb 2021 18:57:23
DataPoint Un-verified.	(b) (4), (b) (6)	
DataPoint Un-verified.	Steven Anderson (b) (4)	27 Jan 2021 20:09:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 20:09:37
DataPoint Verified.	Steven Anderson (b) (4)	27 Jan 2021 16:30:54
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 16:23:45
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:22:50
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:19:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Dec 2020 19:02:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 19:02:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	16 Dec 2020 19:02:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Dec 2020 14:22:15
User entered empty.	System	16 Dec 2020 14:22:15
	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15
	(b) (4)	

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:30:56
DataPoint Un-verified.		27 Jan 2021 16:23:47
DataPoint Verified.		27 Jan 2021 16:22:50
User entered empty.	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 14:22:15

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:57:10
User closed query 'Per source, day 28 saliva sample was collected at day 28 visit. Please confirm and update as appropriate' (Site from CRA).		11 Feb 2021 18:57:04
Query 'Per source, day 28 saliva sample was collected at day 28 visit. Please confirm and update as appropriate' answered with 'this has been updated to indicate that saliva was collected on day 28 visit on 19-Jan-2021' (Site from CRA).	Steven Anderson (b) (4)	27 Jan 2021 20:10:59
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:09:37
	(b) (4)	
User opened query 'Per source, day 28 saliva sample was collected at day 28 visit. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:25:51
DataPoint Un-verified.		27 Jan 2021 16:23:40
DataPoint Verified.		27 Jan 2021 16:22:50
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:19:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 19:02:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 19:02:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	16 Dec 2020 19:02:15
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 14:22:15
User entered empty.	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15
	(b) (4)	

US3412208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	11 Feb 2021 18:57:13
	(b) (4), (b) (6)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 20:09:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:23:42
DataPoint Verified.		27 Jan 2021 16:22:50
User entered empty.	Melissa Fuson (b) (4)	16 Dec 2020 14:22:15
	(b) (4)	

US3412208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:00
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 19:49:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 19:49:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:49:57
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 20:24:41
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:24:41

US3412208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:00
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:24:41

US3412208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:00
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:24:41

US3412208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'SICKD1'	System	11 Dec 2020 19:49:57
User entered empty.	System	10 Dec 2020 20:24:41

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '12:40'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered '10 Dec 2020 12:40'	System	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '161' cm	Melissa Fuson (b) (4)	11 Dec 2020 19:50:43
DataPoint set to visible.	(b) (4) System	11 Dec 2020 19:49:57

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '61' kg	Melissa Fuson (b) (4)	11 Dec 2020 19:50:43
DataPoint set to visible.	(b) (4) System	11 Dec 2020 19:49:57

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '37.0' C	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '90'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'bpm'	System	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '19'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'breaths/min'	System	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '116'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'mmHg'	System	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:29
User entered '68'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'mmHg'	System	10 Dec 2020 20:27:34

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27

US3412208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27

US3412208

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:42
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:51:04

US3412208

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:08:42
User entered '10 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:51:04

US3412208

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:09:00
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 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).		18 Dec 2020 09:08:07
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 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 WAS SHIPPED AND IS ON ACCESSION NUMBER 1F65955' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	16 Dec 2020 13:22:16
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 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)	16 Dec 2020 12:42:51
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 19:51:21

US3412208

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:09:00
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:31:00
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you' answered with 'PER SOURCE OF PPD REQUEST FORMBLOOD DRAWN AND COLLECTION DATE OF 10-DEC-2020 AND PPD REPORTING BACK WAS ACCESSION NUMBER: 1F65955 THE DRAWDATE: 08-DEC-2020 (DO NOT KNOW WHERE THIS DATE CAME FROM.BUT 10-DEC-2020 IS CORRECT DATE' (Site from DM).	Melissa Fuson (b) (4)	18 Dec 2020 15:35:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:08:51
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:08:51

US3412208

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' answered with 'SAMPLE WAS SHIPPED ON ACCESSION NUMBER 1F65955' (Site from DM).	Melissa Fuson (b) (4)	16 Dec 2020 13:23:58
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 10 DEC 2020 is reported under illness Visit in EDC, however the Sample dated 08 DEC 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:22:51
User entered '10 Dec 2020'	Melissa Fuson (b) (4)	11 Dec 2020 19:51:21

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:19:41
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:19:41
User entered '19 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:19:41
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered 'SICKD28'	System	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '19 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 17:30:27
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 17:30:27
User entered '11:26' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:27
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Jan 2021 17:30:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered '19 Jan 2021 11:26'	System	19 Jan 2021 17:30:27
User entered empty.	System	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '160.5' cm	Melissa Fuson (b) (4)	19 Jan 2021 17:30:16
DataPoint set to visible.	(b) (4) System	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '65.5' kg	Melissa Fuson (b) (4)	19 Jan 2021 17:30:16
DataPoint set to visible.	(b) (4) System	19 Jan 2021 17:28:29

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '36.6' C	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '56'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered 'bpm'	System	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User entered '11'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered 'breaths/min'	System	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Jan 2021 17:30:40
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	19 Jan 2021 17:30:40
User entered '100' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Jan 2021 17:30:16
User entered '000'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered 'mmHg'	System	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:20:55
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	19 Jan 2021 17:30:40
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	19 Jan 2021 17:30:40
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	19 Jan 2021 17:30:16
User entered '72'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User entered 'mmHg'	System	19 Jan 2021 17:30:16

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:21:08
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:53

US3412208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:21:08
User entered '19 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:30:53

US3412208

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:21:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:31:09

US3412208

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:06

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
Query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 13:04:35
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).		29 Jan 2021 11:18:51
DataPoint Verified.		27 Jan 2021 16:21:24
User entered '19 Jan 2021'	Melissa Fuson (b) (4)	19 Jan 2021 17:31:09

US3412208

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:32:41

US3412208

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:32:41

US3412208

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	07 Jan 2021 19:32:41

US3412208

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 19:32:41

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 18:35:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:05

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 09:02:39
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:35:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:35:06
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:29:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:05

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:41:42
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	07 Jan 2021 19:33:04
	(b) (4)	

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:41:42
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	07 Jan 2021 19:33:04
	(b) (4)	

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '1'	System	07 Jan 2021 19:33:04

US3412208

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'I'	System	07 Jan 2021 19:33:04

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '160.5' cm	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '65.5' kg	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '25.42677'	System	07 Jan 2021 19:34:31
DataPoint set to visible.	System	07 Jan 2021 19:33:04

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '160.5' cm	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '65.5' kg	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '25.42677'	System	07 Jan 2021 19:34:31
DataPoint set to visible.	System	07 Jan 2021 19:33:04

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '9:31'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '7 Jan 2021 9:31'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '37' C	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '61'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'bpm'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '12'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'breaths/min'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '102'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '60'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '160.5' cm	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '65.5' kg	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '25.42677'	System	07 Jan 2021 19:34:31
DataPoint set to visible.	System	07 Jan 2021 19:33:04

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '10:10'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '7 Jan 2021 10:10'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '97.7' F	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '64'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'bpm'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '18'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'breaths/min'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '106'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '64'	Mason Urban (b) (4)	07 Jan 2021 19:34:31

US3412208

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	07 Jan 2021 19:34:31

US3412208

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:34:49

US3412208

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:34:49

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

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)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mRNA-1273'	System	07 Jan 2021 19:35:10
DataPoint set to visible.	System	07 Jan 2021 19:33:04

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '9:43'	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '7 Jan 2021 9:43'	System	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4)	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'ONCE'	System	07 Jan 2021 19:35:10

US3412208

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 19:35:10

US3412208

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:32:23

US3412208

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:32:23

US3412208

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '9:38'	Mason Urban (b) (4)	07 Jan 2021 19:32:23

US3412208

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '7 Jan 2021 9:38'	System	07 Jan 2021 19:32:23

US3412208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:32:10

US3412208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '7 Jan 2021'	Mason Urban (b) (4)	07 Jan 2021 19:32:10

US3412208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '9:36'	Mason Urban (b) (4)	07 Jan 2021 19:32:10

US3412208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '7 Jan 2021 9:36'	System	07 Jan 2021 19:32:10

US3412208

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 19:35:30

US3412208

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'I'	System	07 Jan 2021 19:35:30

US3412208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	14 Jan 2021 16:32:28

US3412208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered '14 Jan 2021'	Mason Urban (b) (4)	14 Jan 2021 16:32:28

US3412208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	14 Jan 2021 16:32:28

US3412208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered empty.	Mason Urban (b) (4)	14 Jan 2021 16:32:28

US3412208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	14 Jan 2021 16:32:33

US3412208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'I'	System	14 Jan 2021 16:32:33

US3412208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '1'	System	14 Jan 2021 16:32:33
DataPoint set to visible.	System	14 Jan 2021 16:32:33

US3412208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Feb 2021 20:47:32

US3412208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '4 Feb 2021'	Melissa Fuson (b) (4)	08 Feb 2021 20:47:32

US3412208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	08 Feb 2021 20:47:32

US3412208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'OLD29'	System	08 Feb 2021 20:47:32

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '4 Feb 2021'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '08:52'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '4 Feb 2021 08:52'	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '98.2' F	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Feb 2021 17:31:38
User entered '74' reason for change: Data Entry Error	Melissa Fuson (b) (4)	09 Feb 2021 17:31:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:06
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'bpm'	System	09 Feb 2021 17:31:38
User entered empty.	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Feb 2021 17:31:38
User entered '14' reason for change: Data Entry Error	Melissa Fuson (b) (4)	09 Feb 2021 17:31:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:06
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06
	(b) (4)	

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'breaths/min'	System	09 Feb 2021 17:31:38
User entered empty.	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Feb 2021 17:31:38
User entered '102' reason for change: Data Entry Error	Melissa Fuson (b) (4)	09 Feb 2021 17:31:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:06
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06
	(b) (4)	

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	09 Feb 2021 17:31:38
User entered empty.	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Feb 2021 17:31:38
Query 'Data is required. Please provide.' answered by System	System	09 Feb 2021 17:31:38
data change (Site from System).		
User entered '64' reason for change: Data Entry	Melissa Fuson (b) (4)	09 Feb 2021 17:31:38
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 17:31:06
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	09 Feb 2021 17:31:38
User entered empty.	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '4 Feb 2021'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '10:15'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '4 Feb 2021 10:15'	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '98.2' F	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '65'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'bpm'	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 20:15:19
Query 'Data is required. Please provide.' answered by System	System	23 Feb 2021 20:15:19
data change (Site from System).		
User entered '16' reason for change: Data Entry	Andrea Newlands (b) (4)	23 Feb 2021 20:15:19
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Feb 2021 17:54:53
User entered empty; reason for change Data Entry	Steven Anderson (b) (4)	12 Feb 2021 17:54:53
Error	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Feb 2021 17:22:35
Query 'Data is required. Please provide.' answered by System		12 Feb 2021 17:22:35
data change (Site from System).		
User entered '14' reason for change: Data Entry	Steven Anderson (b) (4)	12 Feb 2021 17:22:35
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 17:31:06
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06
	(b) (4)	

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'breaths/min'	System	23 Feb 2021 20:15:19
User entered empty.	System	12 Feb 2021 17:54:53
User entered 'breaths/min'	System	12 Feb 2021 17:22:35
User entered empty.	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '112'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '84'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	09 Feb 2021 17:31:06

US3412208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:55

US3412208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '4 Feb 2021'	Melissa Fuson (b) (4)	09 Feb 2021 17:31:55

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

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)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User entered 'mRNA-1273'	System	09 Feb 2021 17:32:16
DataPoint set to visible.	System	14 Jan 2021 16:32:33

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '4 Feb 2021'	Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '09:39'	Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User entered '4 Feb 2021 09:39'	System	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Left Arm (LEFT ARM)'	Melissa Fuson (b) (4)	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User entered 'ONCE'	System	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 17:32:16

US3412208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:32:51

US3412208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:01:57
User entered 'I'	System	09 Feb 2021 17:32:51

US3412208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Feb 2021 17:53:07

US3412208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered '11 Feb 2021'	Mason Urban (b) (4)	11 Feb 2021 17:53:07

US3412208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	11 Feb 2021 17:53:07

US3412208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered empty.	Mason Urban (b) (4)	11 Feb 2021 17:53:07

US3412208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:36:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Feb 2021 17:53:55

US3412208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'I'	System	11 Feb 2021 17:53:55

US3412208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:55:39

US3412208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:55:39

US3412208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 14:55:39

US3412208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'OLD57'	System	04 Mar 2021 14:55:39

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '08:16'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '04 Mar 2021 08:16'	System	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '36.6' C	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '98'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'bpm'	System	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '14'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'breaths/min'	System	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '120'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '70'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered 'mmHg'	System	04 Mar 2021 14:56:15

US3412208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00

US3412208

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:24

US3412208

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:56:24

US3412208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:43

US3412208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:43

US3412208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
User entered '08:34'	Andrea Newlands (b) (4)	04 Mar 2021 14:56:43

US3412208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:00
User entered '04 Mar 2021 08:34'	System	04 Mar 2021 14:56:43

US3412208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:43:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:12
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	10 Dec 2020 20:32:12
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 17:04:09

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:59:03
User entered		
'USA-US061-2020-mRNA-1273-P301000017'	System	15 Dec 2020 13:57:02
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 13:57:02

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:59:05
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)	14 Dec 2020 15:36:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 15:36:28
Data point term sent to Coder	System	14 Dec 2020 15:34:38
User entered 'Symptomatic COVID-19'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:59:06
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:59:08
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	12 Mar 2021 18:39:27
User closed query 'Per DM CLR: Is this event a confirmed diagnosis of Symptomatic Covid-19?=No. However, this condition is a confirmed COVID infection. Please review and update response as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:05:49
Query 'Per DM CLR: Is this event a confirmed diagnosis of Symptomatic Covid-19?=No. However, this condition is a confirmed COVID infection. Please review and update response as appropriate. Otherwise, provide clarification.' answered with 'pcr swab COVID 19 report from 14 dec 2020 result detected ' (Site from DM).	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:22:29
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:21:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:21:08
User opened query 'Per DM CLR: Is this event a confirmed diagnosis of Symptomatic Covid-19?=No. However, this condition is a confirmed COVID infection. Please review and update response as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:57:54
DataPoint Verified.	(b) (4)	11 Feb 2021 18:59:10
User entered 'No (N)'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 18:59:12
User entered '06 Dec 2020'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:19
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:01:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Jan 2021 17:43:36
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:43:36
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Jan 2021 17:43:28
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:22
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		20 Jan 2021 23:11:01
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED TO RECOVERED / RESOLVED' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:44:06
User entered '23 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:43:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 15:40:14
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		23 Dec 2020 16:53:15
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UNKNOWN HAVE NOT RECEIVED COVID RESULTS' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:43:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:08:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).		30 Dec 2020 15:39:32
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		30 Dec 2020 15:39:23
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:31
User entered 'No (N)'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:32
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:34
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:36
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:42
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:01:44
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:01:46
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:49
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:51
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:01:53
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:10
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:12
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).		23 Dec 2020 16:53:20
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'UPDATED TO NOT RELATED' (Site from Safety).	Melissa Fuson (b) (4)	22 Dec 2020 20:42:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Dec 2020 20:41:10
	(b) (4)	
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:09:32
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:15
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4)	22 Dec 2020 20:41:10
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:02:19
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:23
User entered 'I'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:25
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:27
User entered '0'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 19:02:29
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		20 Jan 2021 23:11:06
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED TO RECOVERED RESOLVED' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:44:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 17:43:28
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 15:40:39
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		23 Dec 2020 16:53:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'HAVE NOT RECEIVED COVID RESULTS YET' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:43:37
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:42:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:08:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 19:02:31
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 15:34:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Feb 2021 17:11:10
User closed query 'Muscle aches not listed in source - please confirm and update. Also add all symptoms resolved by 23 Dec 2020.' (Site from CRA).		13 Feb 2021 17:11:07
Query 'Muscle aches not listed in source - please confirm and update. Also add all symptoms resolved by 23 Dec 2020.' answered with 'all information has been updated per query' (Site from CRA).	Steven Anderson (b) (4)	12 Feb 2021 17:57:08
User entered 'SUBJECT PRESENTED WITH AN ILLNESS THAT HAD AN ONSET OF 06-DEC-2020. SUBJECT PRESENTED WITH MILD COUGH, MODERATE FATIGUE, MILD BODY ACHES, MILD HEADACHES, MODERATE LOSS OF TASTE AND SMELL,N MODERATE RUNNY NOSE, AND MILD NAUSEA. THESE SYMPTOMS HAVE IMPROVED AND SUBJECTS HUSBAND DID TEST POSITIVE FOR COVID-19. SUBJECT HAS NOT TAKEN ANY MEDICATIONS AND HAS NOT HAD ANY TREATMENT OUTSIDE OF BEING TESTED BY OUR SITE. All symptoms were resolved by 23-Dec-2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Feb 2021 17:56:54
User entered 'SUBJECT PRESENTED WITH AN ILLNESS THAT HAD AN ONSET OF 06-DEC-2020. SUBJECT PRESENTED WITH MILD COUGH, MODERATE FATIGUE, MILD BODY ACHES, MILD HEADACHES, MODERATE LOSS OF TASTE AND SMELL,N MODERATE RUNNY NOSE, AND MILD NAUSEA. THESE SYMPTOMS HAVE IMPROVED AND SUBJECTS HUSBAND DID TEST POSITIVE FOR COVID-19. SUBJECT HAS NOT TAKEN ANY MEDICATIONS AND HAS NOT HAD ANY TREATMENT OUTSIDE OF BEING TESTED BY OUR SITE.' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Feb 2021 17:56:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Muscle aches not listed in source - please confirm and update. Also add all symptoms resolved by 23 Dec 2020.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 19:03:58
User entered 'Subject presented with an illness that had an onset of 06-Dec-2020. Subject presented with mild cough, moderate fatigue, mild muscle and body aches, mild headaches, moderate loss of taste and smell,n moderate runny nose, and mild nausea. these symptoms have improved and subjects husband did test positive for COVID-19. Subject has not taken any medications and has not had any treatment outside of being tested by our site.'	Steven Anderson (b) (4)	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 15:34:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:21:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:21:34
	(b) (4)	
Data point term sent to Coder	System	09 Feb 2021 17:20:23
User entered 'INSOMNIA'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User closed query 'Per query response, subject was unable to provide specific date, but was updated with 24 Nov 2020? Please confirm full date is known' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:16:55
Query 'Per query response, subject was unable to provide specific date, but was updated with 24 Nov 2020? Please confirm full date is known' answered with 'subject was contacted again and told site that her insomnia started when her husbands health started to decline on 24nov2020.' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 14:59:52
User opened query 'Per query response, subject was unable to provide specific date, but was updated with 24 Nov 2020? Please confirm full date is known' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 16:51:24
User closed query 'if day is not known please enter as UN NOV 2020' (Site from CRA).		02 Mar 2021 16:51:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Feb 2021 16:36:06
User entered '24 Nov 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:36:06
Query 'if day is not known please enter as UN NOV 2020' answered with 'this has been updated to un. subject was unable to provide a specific day on when the insomnia started' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	12 Feb 2021 18:00:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 18:00:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 18:00:30
User entered 'un Nov 2020' (non-conformant).	Steven Anderson (b) (4) (b) (4)	12 Feb 2021 18:00:30
User opened query 'if day is not known please enter as UN NOV 2020' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 19:09:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Feb 2021 17:22:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Feb 2021 17:22:18
User entered 'Nov 2020' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 17:22:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Feb 2021 17:19:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'UN Nov 2020' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User closed query 'Per DM: ConMed is checked on AE of INSOMNIA; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriately. ' (Site from DM). Query 'Per DM: ConMed is checked on AE of INSOMNIA; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriately. ' answered with 'updated' (Site from DM). User opened query 'Per DM: ConMed is checked on AE of INSOMNIA; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriately. ' (Site from DM). User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 04:07:54
	Andrea Newlands (b) (4)	26 Feb 2021 16:06:18
	(b) (4), (b) (6)	24 Feb 2021 05:55:35
	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:19:48
	(b) (4)	

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 17:19:48

US3412208

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 17:19:48

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:43:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:39:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:46:40

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
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) (b) (4)	21 Aug 2020 17:49:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:49:19
Data point term sent to Coder	System	21 Aug 2020 17:48:07
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '20'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:47:12

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 07:38:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:38:11
Data point term sent to Coder	System	21 Aug 2020 17:48:07
User entered 'MELOXICAM'	(b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'OSTEOARTHRITIS KNEE'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '15'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:47:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 17:50:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:50:21
Data point term sent to Coder	System	21 Aug 2020 17:49:10
User entered 'LEVOTHYROXINE'	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'HYPOTHYROID'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '75'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'UN Dec 2019'	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:48:41

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D 3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'VITAMIN D 3'	(b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'GENERAL HEALTH / BONE HEALTH'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '1000'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:49:19

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'MULTIVITAMIN'	(b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'GENERAL HEALTH'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:49:50

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Aug 2020 13:07:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 13:07:42
Data point term sent to Coder	System	21 Aug 2020 17:52:14
User entered 'DICLOFENAC 170 GEL'	(b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'OSTEOARTHRITIS'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User closed query 'Per DM CLR RQ: Please review and verify if # of application/s will be a more appropriate response for this topical medication instead (e.g., Dose=1, If dose unit is Other, specify= Application, etc.). Please reference the eCRF Guidelines as needed and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 05:25:09
Query 'Per DM CLR RQ: Please review and verify if # of application/s will be a more appropriate response for this topical medication instead (e.g., Dose=1, If dose unit is Other, specify= Application, etc.). Please reference the eCRF Guidelines as needed and update as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 13:48:55
User entered '4' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 13:48:48
User opened query 'Per DM CLR RQ: Please review and verify if # of application/s will be a more appropriate response for this topical medication instead (e.g., Dose=1, If dose unit is Other, specify= Application, etc.). Please reference the eCRF Guidelines as needed and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:27:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit or provide explanation for alternate dosage. ' (Site from DM).		16 Oct 2020 04:07:39
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit or provide explanation for alternate dosage. ' answered with 'PER VIEW SOURCE DOCUMENT IT IS 170 GEL' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Oct 2020 18:58:13
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage and dose unit or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:24:33

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '170'	(b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'g (g)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Oct 2020 13:48:48
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	19 Oct 2020 13:48:48
	(b) (4)	
User entered 'UNK'	(b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:27

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:54:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:54:31
Data point term sent to Coder Coding entries removed.	System Melissa Fuson (b) (4)	14 Oct 2020 18:53:30 14 Oct 2020 18:52:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 17:53:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:53:19
Data point term sent to Coder User entered 'TYLENOL'	System (b) (4), (b) (6)	21 Aug 2020 17:52:15 21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User closed query 'Per DM CLR: Please note that this condition (HEADACHE) is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 04:06:26
Query 'Per DM CLR: Please note that this condition (HEADACHE) is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'HEADACHES FOR SEASONAL ALLERGIES WHICH IS LISTED IN MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Oct 2020 18:52:59
User entered 'HEADACHES FOR SEASONAL ALLERGIES' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Oct 2020 18:52:39
User opened query 'Per DM CLR: Please note that this condition (HEADACHE) is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:58:46
User entered 'HEADACHES WITH ALLERGIES'	(b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '500'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 17:51:58

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 12:51:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:51:18
Data point term sent to Coder	System	23 Sep 2020 12:48:06
User entered 'Triamcinolone'	(b) (4), (b) (6) (b) (4) (b) (4)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
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). 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 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 05:23:12
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). User entered 'Rash from mask'	Jacob sekinger (b) (4) (b) (4) (b) (4), (b) (6)	19 Oct 2020 13:51:45 19 Oct 2020 02:28:35 23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User closed query 'Per DM CLR: Please note 0.1% is the drug concentration which should be entered with the Drug Name. Please update the Dose and Unit fields to the # of applications instead. Please review and update eCRF accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 05:23:32
Query 'Per DM CLR: Please note 0.1% is the drug concentration which should be entered with the Drug Name. Please update the Dose and Unit fields to the # of applications instead. Please review and update eCRF accordingly.' answered with 'this information is not known.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 13:55:05
User opened query 'Per DM CLR: Please note 0.1% is the drug concentration which should be entered with the Drug Name. Please update the Dose and Unit fields to the # of applications instead. Please review and update eCRF accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:29:01
User entered '0.1'		23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '%'	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:43
User entered 'UN UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 12:47:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:38
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:38
User entered ' UNK 2020' (non-conformant).	(b) (4), (b) (6)	23 Sep 2020 12:47:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:30
User entered ' 2020' (non-conformant).	(b) (4), (b) (6)	23 Sep 2020 12:47:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 12:47:22
User entered 'UN 2020' (non-conformant).	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 12:47:22

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 21:40:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:40:06
Data point term sent to Coder	System	22 Feb 2021 21:39:57
User entered 'tylenol'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 21:39:04

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN LEFT SHOULDER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN LEFT SHOULDER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 01:42:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION PAIN LEFT SHOULDER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION PAIN LEFT SHOULDER did not meet the AE reporting criteria. ' answered with 'did not meet reporting criteria' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 15:00:46

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '500'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '07 Jan 2021'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:04
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:04

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:04

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:04

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 16:07:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 16:07:52
Data point term sent to Coder Coding entries removed.	System	26 Feb 2021 16:07:06
	Andrea Newlands (b) (4)	26 Feb 2021 16:06:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 21:40:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 21:40:07
Data point term sent to Coder User entered 'melatonin'	System	22 Feb 2021 21:39:57
	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response noted; However there is ongoing medical condition of insomnia in AE eCRF. Please review if this field should be updated to 'No' as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:34:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
Query 'Per CDM re-query: Response noted; However there is ongoing medical condition of insomnia in AE eCRF. Please review if this field should be updated to 'No' as appropriate else clarify. ' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:28:54
User opened query 'Per CDM re-query: Response noted; However there is ongoing medical condition of insomnia in AE eCRF. Please review if this field should be updated to 'No' as appropriate else clarify. ' (Site from DM).		25 Mar 2021 07:59:29
Query 'Per CDM re-query: Response noted; However there is ongoing medical condition of insomnia in AE eCRF. Please review if this field should be updated to 'No' as appropriate else clarify. ' canceled (Site from DM).		25 Mar 2021 07:58:41
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).		25 Mar 2021 07:58:27
User opened query 'Per CDM re-query: Response noted; However there is ongoing medical condition of insomnia in AE eCRF. Please review if this field should be updated to 'No' as appropriate else clarify. ' (Site from DM).		25 Mar 2021 07:58:24
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'RELATED TO AE MEDICATION PRESCRIBED FOR PREVENTIVE CARE' (Site from DM).		24 Mar 2021 19:04:03

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4) Andrea Newlands (b) (4)	14 Mar 2021 14:03:01 22 Feb 2021 21:39:44

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'insomnia' reason for change: Data Entry Error	Andrea Newlands (b) (4)	26 Feb 2021 16:06:09
	(b) (4)	
User entered 'general health'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '5'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '04 Feb 2021'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:21:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	22 Feb 2021 21:39:44
	(b) (4)	

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:44

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:44

US3412208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:43:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 21:39:44

US3412208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:43:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:39:20
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 17:46:31

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	09 Apr 2021 12:28:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '15/Dec/2020 07:59'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered '1'		15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '23/Dec/2020 16:53'	System	23 Dec 2020 16:53:49

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4)	09 Apr 2021 12:28:42
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:45:45
User entered 'I'		23 Dec 2020 16:53:49

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '28/Dec/2020 12:45'	System	28 Dec 2020 17:45:55

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		20 Jan 2021 23:11:19
User entered '1'		28 Dec 2020 17:45:55

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '20/Jan/2021 18:11'	System	20 Jan 2021 23:11:29

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		20 Jan 2021 23:11:35
User entered '1'		20 Jan 2021 23:11:29

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '18/Feb/2021 08:47'	System	18 Feb 2021 13:47:37

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		18 Feb 2021 13:47:47
User entered '1' reason for change: New Information		18 Feb 2021 13:47:37
User entered '0'		20 Jan 2021 23:11:44

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '18/Feb/2021 08:56'	System	18 Feb 2021 13:56:27

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		18 Feb 2021 13:57:01
User entered '1'		18 Feb 2021 13:56:27

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'USA-US061-2020-MRNA-1273-P301000017'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'No (N)'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gregory'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Gottschlich'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered 'Cincinnati'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		15 Dec 2020 13:59:15
User entered '45242'	System	15 Dec 2020 13:57:02

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
Reviewed for Safety.		23 Dec 2020 16:53:37
User entered 'US'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	18 Mar 2021 18:01:55
User entered '6'	System	18 Feb 2021 13:56:27
User entered '5'	System	18 Feb 2021 13:47:37
User entered '4'	System	20 Jan 2021 23:11:29
User entered '3'	System	28 Dec 2020 17:45:55
User entered '2'	System	23 Dec 2020 16:53:49
User entered '1'	System	15 Dec 2020 13:59:28

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 22:43:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered '18/Mar/2021 14:01'	System	18 Mar 2021 18:01:55

US3412208

Folder: SAE USA-US061-2020-MRNA-1273-P301000017

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 22:43:06

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.	Richard Powell (b) (4)	16 Apr 2021 14:41:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:28:42
User entered 'I'		18 Mar 2021 18:01:55